

EPA Reg. Jacket 5383-193

## Heffernan, Aline

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**From:** Heffernan, Aline  
**Sent:** Wednesday, June 21, 2017 9:22 AM  
**To:** 'Miksztal, Maureen'  
**Subject:** RE: Troy feedback on 5383-193 - CSF withdrawn by registrant

Maureen,

Both of the amendments were withdrawn.

Thank you,  
Aline

**From:** Miksztal, Maureen [mailto:miksztalm@troycorp.com]  
**Sent:** Wednesday, June 21, 2017 9:17 AM  
**To:** Heffernan, Aline <heffernan.aline@epa.gov>  
**Subject:** Troy feedback on 5383-193 - CSF withdrawn by registrant

6/21/2017

Aline,

Thank you for your note. Yes, please withdraw the CSF amendments due to non-standard certified limits and label uses.

Regards,

*Maureen*

Maureen Miksztal  
Senior Regulatory Manager  
Product Registration  
Troy Corporation | 8 Vreeland Road | Florham Park NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile



This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error, please notify the sender immediately and delete this e-mail from your system. If you are not the intended recipient, you are notified that disclosing, copying, distributing, or taking any action on the contents of this information is strictly prohibited.

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**From:** Heffernan, Aline [mailto:heffernan.aline@epa.gov]  
**Sent:** Friday, June 16, 2017 2:27 PM

**To:** Miksztal, Maureen  
**Subject:** RE: 5383-193

Maureen,

I have been working on your CSF amendments for 5383-193 and there are a few things that need to change.

On Alternate 1, the last source has different certified limits that the product so it is not allowed on the CSF. This would make it identical to the alternate 1 CSF that we have on file if this is removed.

On Alternate 2, there are several use sites that are not on both labels including: [REDACTED]

[REDACTED] From what I understand about [REDACTED]

[REDACTED] Therefore this source would not be allowed on the CSF.

Given the changes to the CSFs are unacceptable would you like to withdraw both of the CSF Amendments that were submitted?

Thank you,  
Aline

**From:** Heffernan, Aline  
**Sent:** Friday, June 02, 2017 9:44 AM  
**To:** 'Miksztal, Maureen' <miksztalm@troycorp.com>  
**Subject:** RE: 5383-193/192

5383-192 has not been assigned yet so I have not taken a look at the CSFs yet. The information I gave was for 5383-193, the 50% product.

Aline

**From:** Miksztal, Maureen [mailto:miksztalm@troycorp.com]  
**Sent:** Friday, June 02, 2017 9:38 AM  
**To:** Heffernan, Aline <heffernan.aline@epa.gov>  
**Subject:** RE: 5383-193/192

Thank you. I am only referring to the 50% action and not the 25% which is where there is a rounding error.

Maureen

**From:** Heffernan, Aline [mailto:heffernan.aline@epa.gov]  
**Sent:** Friday, June 02, 2017 9:05 AM  
**To:** Miksztal, Maureen  
**Subject:** RE: 5383-193/192

Maureen,

It is not possible to reconsider an alternate timing. If the action is assigned to me, I will likely be able to get it to you before the 3 month deadline but if it isn't I cannot speak for the other reviewers on my team.

I have taken a look at the products again and there are differences in the certified limits that go beyond rounding errors.

Thank you,  
Aline

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
**Sent:** Thursday, June 01, 2017 4:49 PM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Subject:** RE: 5383-193/192

Ok. Is it possible to consider alternate timing since the initial submission was inappropriately rejected based on the labeling?

Thanks for all of your help.

Maureen

**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Thursday, June 01, 2017 4:29 PM  
**To:** Miksztal, Maureen  
**Subject:** RE: 5383-193/192

The official timeline is a three month review. If it gets assigned to me, I should be able to turn it around faster. At this time however there is no guarantee that it will be assigned to me.

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
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**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Subject:** RE: 5383-193/192

What will the timeline be for the 50% product this was denied in error?

**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Thursday, June 01, 2017 11:06 AM  
**To:** Miksztal, Maureen  
**Cc:** Murasaki, Seiichi  
**Subject:** 5383-193/192

Maureen,

Thank you for the call this morning and this is a follow up as per our discussion.

For 5383-192, the 25% product, please resubmit the corrected cover letter through the portal. If the package has been submitted please do not resubmit the entire data package, just resubmit the cover letter. If the product was submitted this morning or earlier this week it might take a few days to get into our system for the resubmission to be possible.

For 5383-193, the 50% product, please remove the source we discussed. I've checked the other sources on the CSF as well. The second source on the CSF from [REDACTED] And the third source also from [REDACTED] In other words only the first source listed on the CSF would be acceptable. Please resubmit the whole action with these changes.

I will include this email exchange in the jacket so if another reviewer is assigned the action they will know what we talked about.



Thank you,

Aline Heffernan  
Regulatory Management Branch 1  
Antimicrobials Division  
Office of Pesticide Programs  
703-347-8602

 <b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b> <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other:</b>	OPP Identifier Number <div style="font-size: 1.5em; letter-spacing: 0.5em;">XXXXXX</div>
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**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No  Product Name

**Section - II**

<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated 5/4/2016 <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Troy Corporation is submitting a CSF amendment.

**Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Unit Packaging wt.      container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Package wgt.      container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* <b>Certification must be submitted</b>			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Maureen Mikszta	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (973) 443-4200 ext. 2285
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title Senior Regulatory Manager	
4. Typed Name Maureen Mikszta	5. Date 5/15/2017	

DOCUMENTUM



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**TROY CORPORATION**

May 15, 2017

Via CDX

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: **MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193**  
**Alternate CSF amendment**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits a CSF amendment for an additional alternate for MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193. The only change to the CSF is the registered source of active ingredient. Note: this action is eligible for formulators' exemption since all formulations are 100% repack of a different registered source.

This submission includes the following information using CDX:

- EPA Form 8570-1 Amendment Application
- EPA Form 8570-4 Proposed Alternate Confidential Statement of Formula 2
- EPA Form 8570-4 Current Basic Confidential Statement of Formula
- EPA Form 8570-27 Formulators Exemption

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/11/2016
- Alternate CSF 1 dated 5/7/2016

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

Enclosure

2006-05-15



United States Environmental Protection Agency  
Washington, D.C. 20460

**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address Troy Chemical Corporation One Avenue L, Newark, N.J. 07105 c/o Troy Corporation 8 Vreeland Rd. Florham Park, N.J. 07932	EPA File Symbol/Registration Number <b>5383-193</b> Product Name <b>MERGAL GLT50</b> Date of Confidential Statement of Formula (EPA Form 8570-4) <b>May 31, 2017</b>
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As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

**Glutaraldehyde**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:



(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**



(B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Glutaraldehyde, 50%	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
Glutaraldehyde, 50%	[REDACTED]	[REDACTED]
	OR	OR
Glutaraldehyde, 50%	[REDACTED]	[REDACTED]
	OR	OR
Glutaraldehyde, 50%	[REDACTED]	[REDACTED]
	OR	OR
Signature <i>Maureen Mikszta</i>	Name and Title Maureen Mikszta Senior Regulatory Manager	Date 5/31/2017

 <b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b> <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other:</b>	OPP Identifier Number <div style="font-size: 1.5em; text-align: center;">XXXXXX</div>
---	--	--

**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u><b>PLEASE SEND ALL CORRESPONDENCE TO</b></u> <u><b>"CONTACT POINT" LISTED BELOW</b></u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____

**Section - II**

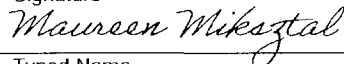
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**Amend Alternate CSF1****Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Unit Packaging wt.      container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Package wgt.      container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
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**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name <b>Maureen Mikszta</b>	Title <b>Senior Regulatory Manager</b>	Telephone No. (Include Area Code) <b>(973) 443-4200 ext. 2285</b>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title <b>Senior Regulatory Manager</b>		
4. Typed Name <b>Maureen Mikszta</b>	5. Date <b>5/31/2017</b>		



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**TROY CORPORATION**

May 31, 2017

Via CDX

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193  
**CSF Amendment- Alternate CSF1**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits an amendment to alternate **CSF1** for MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193. The revision to alternate **CSF1** is to add an additional registered source of active ingredient. This action is eligible for the formulators' exemption since it is a 100% repack of the new source.

This submission includes the following information using CDX:

- EPA Form 8570-1 Application for Registration
- EPA Form 8570-4 Proposed Alternate Confidential Statement of Formula 1
- EPA Form 8570-4 Current Alternate Confidential Statement of Formula 1
- EPA Form 8570-27 Formulators Exemption

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/11/2016
- Alternate CSF 1 dated 5/7/2016

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

DOCUMENTUM





Applicant's Name and Address  
Troy Chemical Corporation  
One Avenue L, Newark, N.J. 07105  
c/o  
Troy Corporation  
8 Vreeland Rd. Florham Park, N.J. 07932

5383-193

Product Name

**MERGAL GLT50**

Date of Confidential Statement of Formula (EPA Form 8570-4)

6/1/2017

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

☒ (A) An accurate Confidential Statement of Formula (*EPA Form 8570-4*) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

<i>Source</i>		
<b>Active Ingredient</b>	<b>Product Name</b>	<b>Registration Number</b>
<b>Glutaraldehyde, 50%</b>	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED] [REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
<b>Signature</b> <i>Maureen Mikształ</i>	<b>Name and Title</b> Maureen Mikształ Senior Regulatory Manager	<b>Date</b> 6/1/2017

EPA Form 8570-27 (Rev. 7-91)

White - EPA copy

Yellow - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*

## Heffernan, Aline

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**From:** Heffernan, Aline  
**Sent:** Friday, June 02, 2017 9:44 AM  
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**Subject:** RE: 5383-193/192

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**Cc:** Murasaki, Seiichi  
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For 5383-193, the 50% product, please remove the source we discussed. I've checked the other sources on the CSF as well. The second source on the CSF from [REDACTED] And the third source also from [REDACTED] In other words only the first source listed on the CSF would be acceptable. Please resubmit the whole action with these changes.

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Aline Heffernan  
Regulatory Management Branch 1  
Antimicrobials Division  
Office of Pesticide Programs  
703-347-8602

\*Product ingredient source information may be entitled to confidential treatment\*

**Heffernan, Aline**

---

**From:** Miksztal, Maureen <miksztalm@troycorp.com>  
**Sent:** Monday, May 29, 2017 10:34 PM  
**To:** Heffernan, Aline  
**Cc:** Murasaki, Seiichi  
**Subject:** Replacements documents for alternate CSF amendment (5383-193)  
**Attachments:** MERGAL GLT50\_altcsf2\_5383-193\_052917 signed.pdf; EPA8570-27 (Formulator'sExemption Statement) MERGAL GLT50 signed.pdf

**Discard earlier message from today.**

**Business Confidential**

5/29/2017

Regards,

**\*Claimed confidential by submitter\***

*Maureen*

Maureen Miksztal  
Senior Regulatory Manager  
Product Registration  
Troy Corporation | 8 Vreeland Road | Florham Park NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile



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*This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error, please notify the sender immediately and delete this e-mail from your system. If you are not the intended recipient, you are notified that disclosing, copying, distributing, or taking any action on the contents of this information is strictly prohibited.*

---

**From:** Heffernan, Aline [mailto:heffernan.aline@epa.gov]  
**Sent:** Friday, May 26, 2017 12:48 PM  
**To:** Miksztal, Maureen  
**Cc:** Murasaki, Seiichi  
**Subject:** RE: EPA Completed Action (5383-193) Unacceptable

Maureen,

It is the second source on the CSF dated 5/15 and it is also 6<sup>th</sup> source that is listed on the formulator's exemption form.

As a note the second source on the formulator's exemption form, is not accepted. It is the product that has two reg. numbers, the first one listed is not on an approved CSF.

If you are still unsure on which products I am talking about I will be happy to call to give you the reg. numbers. I don't want to disclose them as the Agency cannot secure any CBI that is sent over email.

Thank you,

Aline

**From:** Miksztal, Maureen [mailto:miksztalm@troycorp.com]  
**Sent:** Friday, May 26, 2017 11:29 AM  
**To:** Heffernan, Aline <heffernan.aline@epa.gov>  
**Cc:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>  
**Subject:** Re: EPA Completed Action (5383-193) Unacceptable

I do have questions. Please confirm which one of the sources is in question with different limits. I will take that off and we can get the others on the CSF.

Thank you  
Maureen

Sent from my iPhone

On May 26, 2017, at 4:43 PM, "Heffernan, Aline" <heffernan.aline@epa.gov> wrote:

Maureen,

I spoke with Seiichi and we decided the uses since they would not require new data they would fall under the same use categories that are on the label. I looked into the jackets for the products that are on the CSF there is an issue with the second source. The certified limits for that source are different than the



certified limits on the CSF. If a source would not be accepted, all sources for a 100% repack have to have the same certified limits.

Please let me know if you have any other questions,

Aline

**From:** Heffernan, Aline  
**Sent:** Wednesday, May 24, 2017 2:42 PM  
**To:** 'Miksztal, Maureen' <miksztalm@troycorp.com>  
**Cc:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>  
**Subject:** RE: EPA Completed Action (5383-193) Unacceptable

Maureen,

I will discuss it with Seiichi tomorrow since it looks like he is the one who originally signed off on the formulator's exemption. My concern is that the products that are on the formulator's exemption that have the uses are not on the CSFs. I am not sure if there has been adequate data compensation for these uses if the product is not actually being purchased.

Aline

**From:** Miksztal, Maureen [mailto:miksztalm@troycorp.com]  
**Sent:** Tuesday, May 23, 2017 5:51 PM  
**To:** Heffernan, Aline <heffernan.aline@epa.gov>  
**Subject:** Re: EPA Completed Action (5383-193) Unacceptable

Thank you for your explanation. Have you looked in the jacket to review how these uses were added. They are an extension of the [REDACTED] which is on all three labels. Please review the earlier label amendment approved by EPA. The same scenario is applicable here.

Please comment.

Thank you.

Maureen Miksztal

Sent from my iPhone

On May 23, 2017, at 2:31 PM, "Heffernan, Aline" <heffernan.aline@epa.gov> wrote:

Maureen,

All three of the sources on the CSF are missing the same three uses. The labels does not have the [REDACTED]

Since these uses are not on the alternate sources there either needs to be data comp to the sources that do have these sites or the label for 5383-193 should be edited so those use sites are removed.

\*Product ingredient source information may be entitled to confidential treatment\*



If you have any other questions please let me know and I would be happy to discuss it further with you.

Thank you,

Aline

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
**Sent:** Saturday, May 20, 2017 2:51 AM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Subject:** Fwd: EPA Completed Action (5383-193) Unacceptable

Good morning. Thank you for the quick response.

Please let me know what use site you are referring to and which product? They all have same use profiles and are 100percent repack.

Thank you,

Maureen

Sent from my iPhone

Begin forwarded message:

**From:** "Heffernan, Aline" <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Date:** May 19, 2017 at 3:28:20 PM GMT+2  
**To:** "Miksztal, Maureen" <[miksztalm@troycorp.com](mailto:miksztalm@troycorp.com)>  
**Cc:** OPP AD Ombudsman <[OPP\\_AD\\_Ombudsman@epa.gov](mailto:OPP_AD_Ombudsman@epa.gov)>, "Hebert, John" <[Hebert.John@epa.gov](mailto:Hebert.John@epa.gov)>, "Murasaki, Seiichi" <[Murasaki.Seiichi@epa.gov](mailto:Murasaki.Seiichi@epa.gov)>  
**Subject:** EPA Completed Action (5383-193) Unacceptable

Maureen,

Please see attached letter and let me know if you have any questions or comments.

Thank you,

Aline Heffernan  
Regulatory Management Branch 1  
Antimicrobials Division  
Office of Pesticide Programs  
703-347-8602

## Heffernan, Aline

---

**From:** Murasaki, Seiichi  
**Sent:** Wednesday, May 31, 2017 3:20 PM  
**To:** Miksztal, Maureen  
**Cc:** Golick, Patti; Heffernan, Aline  
**Subject:** RE: Request to withdraw basic CSF amendment - CDX\_2017\_003515 and and Receipt number: 1003842

Maureen,

I am confirming receipt of your request to withdraw submission 1003842 for EPA Reg. # 5383-193.

Seiichi Murasaki  
Regulatory Management Branch I  
Antimicrobials Division  
Office of Pesticide Programs  
Environmental Protection Agency  
703-347-0163

**From:** Miksztal, Maureen [mailto:miksztalm@troycorp.com]  
**Sent:** Wednesday, May 31, 2017 2:20 PM  
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>  
**Cc:** Golick, Patti <GolickP@troycorp.com>  
**Subject:** Request to withdraw basic CSF amendment - CDX\_2017\_003515 and and Receipt number: 1003842

5/31/2017

Seiichi,

Hello. Hope you are doing well.

Troy would like to withdraw the basic CSF amendment for Mergal GLT50 submitted on 5/19/17 and assigned tracking number CDX\_2017\_003515 and Receipt number: 1003842.

By return email confirm receipt of request to withdraw basic CSF amendment.

Thank you.

Regards,

*Maureen*

Maureen Miksztal  
Senior Regulatory Manager  
Product Registration  
Troy Corporation | 8 Vreeland Road | Florham Park NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile



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*This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error, please notify the sender immediately and delete this e-mail from your system. If you are not the intended recipient, you are notified that disclosing, copying, distributing, or taking any action on the contents of this information is strictly prohibited.*

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**From:** [helpdesk@epacdx.net](mailto:helpdesk@epacdx.net) [mailto:[helpdesk@epacdx.net](mailto:helpdesk@epacdx.net)]  
**Sent:** Monday, May 22, 2017 12:16 PM  
**To:** Golick, Patti  
**Subject:** CDX PSP Package Status Update: Milestone 1 Completed

The status of your PSP package (Mergal GLT50) is: Milestone 1 Completed.

Below are the application(s) included in this package and their tracking number(s):  
Sec3-Amend-000001: CDX\_2017\_003515

Company Name: TROY CORPORATION  
Company Number: 5383

If you have questions concerning this message, you may contact the CDX Help Desk by email at [helpdesk@epacdx.net](mailto:helpdesk@epacdx.net) or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage  
<https://cdx.epa.gov>

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United States Environmental Protection Agency - Central Data Exchange



**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address Troy Chemical Corporation One Avenue L, Newark, N.J. 07105 c/o Troy Corporation 8 Vreeland Rd. Florham Park, N.J. 07932	EPA File Symbol/Registration Number <b>5383-193</b>
	Product Name <b>MERGAL GLT50</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>May 29, 2017</b>

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

**Glutaraldehyde**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:



(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**



(B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Glutaraldehyde, 50%	[Redacted]	[Redacted]
	OR	OR
	[Redacted]	[Redacted]
	OR	OR
	[Redacted]	[Redacted]
	OR	OR
	[Redacted]	[Redacted]
	OR	OR
Signature <i>Maureen Mikszta</i>	Name and Title Maureen Mikszta Senior Regulatory Manager	Date 5/29/2017

**EPA**

United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ **Registration**  
☒ **Amendment**  
☐ **Other:**

OPP Identifier Number  
 XXXXXX

**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <b><u>PLEASE SEND ALL CORRESPONDENCE TO</u></b> <b><u>"CONTACT POINT" LISTED BELOW</u></b> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No  Product Name

**Section - II**

- ☒ Amendment – Explain below. ☐ Final printed labels in response to Agency letter dated 5/4/2016  
☐ Resubmission in response to Agency letter dated \_\_\_\_\_ ☐ "Me Too" Application  
☐ Notification - Explain below. ☐ Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Troy Corporation is submitting a CSF amendment.

**Section - III****1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging

- ☐ Yes\*  
☒ No

Unit Packaging

- ☐ Yes  
☒ No

Water Soluble Packaging

- ☐ Yes  
☒ No

**2. Type of Container**

- ☐ Metal  
☒ Plastic  
☐ Glass  
☐ Paper  
☐ Other (Specify)

**\*Certification must be submitted**

If "Yes" Unit Packaging wt. No. per container

If "Yes" Package wgt. No. per container

**3. Location of Net Contents Information**

- ☒ Label ☐ Container

**4. Size(s) Retail Container**

40 lb pail, 100 lb and 450 lb drum,  
 2200 lb tote and bulk

**5. Location of Label Directions**

- ☒ On Label  
☐ On labeling accompanying product

**6. Manner in Which Label is Affixed to Product**

- ☐ Lithograph ☐ Other \_\_\_\_\_  
☒ Paper glued  
☐ Stenciled

**Section - IV****1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)**

Name Maureen Mikszta	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (973) 443-4200 ext. 2285
-------------------------	------------------------------------	---

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**2. Signature***Maureen Mikszta***3. Title**

Senior Regulatory Manager

**4. Typed Name**

Maureen Mikszta

**5. Date**

5/17/2017

**6. Date Application Received**  
**(Stamped)**



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**TROY CORPORATION**

May 17, 2017

Via CDX

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193  
**Basic CSF amendment**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits a basic CSF amendment for MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193. The purpose of this CSF is to allow sourcing from more than one supplier. The modifications to the CSF include an alternate registered source of active ingredient and a nominal adjustment in the upper certified limit to accommodate this change. Note: this action is eligible for formulators' exemption since the formulation is a 100% repack of registered sources.

This submission includes the following information using CDX:

- EPA Form 8570-1 Amendment Application
- EPA Form 8570-4 Proposed Confidential Statement of Formula
- EPA Form 8570-4 Current Basic Confidential Statement of Formula
- EPA Form 8570-27 Formulators Exemption

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/11/2016
- Alternate CSF 1 dated 5/7/2016

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

DOCUMENTUM





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 19, 2017

Maureen Miksztal  
Senior Regulatory Manager  
Troy Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

Subject: CSF Amendment – Adding an Alternate CSF  
Product Name: Mergal GLT50  
EPA Registration Number: 5383-193  
Application Date: 05/15/2017  
Decision Number: 529556

Dear Ms. Miksztal:

The Confidential Statement of Formulation referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is not acceptable for the following reason:

1. The sources of AI do not have all the uses as the product label. No data matrix submitted to support these uses.

Therefore, your application is not acceptable. No further processing of this application will occur. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at [heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "John Hebert", is written over a horizontal line.

John Hebert, Chief  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs



**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address Troy Chemical Corporation One Avenue L, Newark, N.J. 07105 c/o Troy Corporation 8 Vreeland Rd. Florham Park, N.J. 07932	EPA File Symbol/Registration Number <b>5383-193</b>
	Product Name <b>MERGAL GLT50</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>May 15, 2017</b>

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

**Glutaraldehyde**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:


☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Glutaraldehyde, 50%	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
Signature <i>Maureen Miksztal</i>	Name and Title Maureen Miksztal Senior Regulatory Manager	Date 5/15/2017

 <b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b> <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other:</b>	OPP Identifier Number <div style="font-size: 1.5em; text-align: center;">XXXXXX</div>
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**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u><b>PLEASE SEND ALL CORRESPONDENCE TO</b></u> <u><b>"CONTACT POINT" LISTED BELOW</b></u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No _____  Product Name _____

**Section - II**

<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated 5/4/2016 <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Troy Corporation is submitting a CSF amendment.

**Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Unit Packaging wt.      container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Package wgt.      container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Maureen Mikszta	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (973) 443-4200 ext. 2285	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title Senior Regulatory Manager		
4. Typed Name Maureen Mikszta	5. Date 5/15/2017		



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**TROY CORPORATION**

May 15, 2017

Via CDX

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL® GLT50, EPA Reg. No. 5383-193  
**Alternate CSF amendment**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits a CSF amendment for an additional alternate for MERGAL® GLT50, EPA Reg. No. 5383-193. The only change to the CSF is the registered source of active ingredient. Note: this action is eligible for formulators' exemption since all formulations are 100% repack of a different registered source.

This submission includes the following information using CDX:

- EPA Form 8570-1 Amendment Application
- EPA Form 8570-4 Proposed Alternate Confidential Statement of Formula 2
- EPA Form 8570-4 Current Basic Confidential Statement of Formula
- EPA Form 8570-27 Formulators Exemption

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/11/2016
- Alternate CSF 1 dated 5/7/2016

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

Enclosure

Receipt for Section 3

S: 985850

Milestone Email: mikszta@m@troycorp.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Company: 5383 TROY CHEMICAL CORPORATION

☒

Risk Manager: Antimicrobials Division, Risk Management Team 33

☐

Product #: 5383-193

Product Name: MERGAL GLT50

Override#:

Me Too Section3: 88951-2

Me Too Product Name: PANAX 500 50

Application Date: 05-May-2016

OPP Rec'd Date: 06-May-2016

Front End Date: 06-May-2016

Risk Manager Send Date: 06-May-2016

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Portal # 11439 Final Printed Labeling.

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Electronic Label

View/Edit

New Ingredient Request Date

New Ingredient Received Date

DOCUMENTUM



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**TROY CORPORATION**

May 6, 2016

Via E-Portal

Document Processing Desk (REG)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL® GLT50, EPA Reg. No. 5383-193  
Submission of Final Printed Labelling  
Agency correspondence dated May 4, 2016

Dear Ms. Chao:

Troy Corporation, on behalf of Troy Chemical Corporation, hereby submits the final printed labeling for the product referenced above. This submission addresses the Agency correspondence dated May 4, 2016 approving the new registration for MERGAL® GLT50. We enclose the following documents for this purpose.

- One (1) copy of the final printed label for MERGAL® GLT50
- Copy of agency correspondence dated May 4, 2016 – Approval of registration
- EPA Form 8570-1

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or (973)443-4200 ext. 2285.

Sincerely,


*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

Enclosure

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 <b>EPA</b> United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other:</b>	OPP Identifier Number <div style="text-align: center; font-size: 1.2em;">XXXXXX</div>
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**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u><b>PLEASE SEND ALL CORRESPONDENCE TO</b></u> <u><b>"CONTACT POINT" LISTED BELOW</b></u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No _____  Product Name _____


**Section - II**

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 5/4/2016 <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.)  <b>Submission of final printed labels per agency letter 5/4/2016</b>	

**Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.    No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name <b>Maureen Mikszta</b>	Title <b>Senior Regulatory Manager</b>	Telephone No. (Include Area Code) <b>(973) 443-4200 ext. 2285</b>
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title <b>Senior Regulatory Manager</b>	
4. Typed Name <b>Maureen Mikszta</b>	5. Date <b>5/6/2016</b>	

DOCUMENTUM

# PROCESSING REQUEST

**Reg #** 5383-193

**Decision #** 520747

**Description:** Updated Basic CSF

**Electronic Label & Letter**  
(see PPLS):

OR

**Non Electronic  
Label & Letter**  
(Scanning required):

☐ Dated:

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent** (see jacket):

☒ New CSF(s) Dated: 8/11/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

**Reviewer:** Julie Chao

**Division:** AD/RMB1

**Phone:** 308-8735

**Date:** 8/29/16



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION**

January 10, 2017

Maureen Miksztal  
Senior Regulatory Manager  
Troy Chemical Corporation  
c/o Troy Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

Subject: Label Amendment – Updated Label Language  
Product Name: Mergal GLT50  
EPA Registration Number: 5383-193  
Application Date: June 14, 2016  
Decision Number: 518480

Dear Ms. Miksztal:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

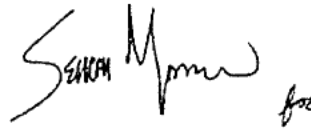
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2  
EPA Reg. No. 5383-193  
Decision No. 518480

with FIFRA section 6. If you have any questions, please contact Emilia Oiguenblik by phone at 703 347 0199, or via email at [Oiguenblik.emilia@epa.gov](mailto:Oiguenblik.emilia@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "John Hebert", with a small "for" written below the signature.

John Hebert, Chief  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped label

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER**

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if inhaled. Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes on skin or on clothing. Avoid breathing vapor. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none"> <li>Wash immediately and continuously with flowing water for at least 30 minutes</li> <li>Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist.</li> <li>Call a poison control center or a doctor immediately for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED:	<ul style="list-style-type: none"> <li>Call a poison control center or doctor for treatment advice.</li> <li>Do not induce vomiting.</li> <li>Do not give anything to drink.</li> </ul>
IF INHALED:	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the MSDS and, if available, the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN:	
Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.	

# Mergal®GLT50

Microbicide for use in Air Washers, Coatings, Concrete Admixtures, Conveyor Lubricants, Completion and Drilling Fluids, Frac Fluids, Gas and Storage Wells, Heat Transfer Systems, Hydrotesting, Industrial, Institutional and Consumer In-can Processes and Products, Metalworking Fluids, Oil and Gas Production, Packer Fluids, Paper Mills, Pigment and Filler Slurries, Pipeline, Piggings and Scraping, Process Water, Raw Material Clean-up, Reverse Osmosis Membranes, Service Water and Auxiliary Systems, Wastewater Systems and Water floods.

EPA Reg. No.	5383-193
EPA Establishment Number	35978-TX-001

ACTIVE INGREDIENT: .....% Weight  
Glutaraldehyde.....50.0%  
INERT INGREDIENTS .....50.0%  
TOTAL.....100.0%

**ACCEPTED**

Jan 10, 2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 5383-193

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

FOR USE IN INDUSTRIAL PROCESSES ONLY

See Side Panel for Additional Precautionary Statements

IN CASE OF EMERGENCY: CALL CHEMTREC 1-800-424-9300

Net Weight:

Sold by:

**Troy Chemical Corporation**  
One Avenue L, Newark, N.J. 07105

**DIRECTIONS FOR USE**

*It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.* In order to determine the most cost effective use level for Mergal®GLT50 in a given use, field trials are suggested.

**Water Based Coatings (For use in non-food contact coatings only):** Use from 0.1 to 0.6 pounds of Mergal GLT50 per 1,000 pounds dry powder to produce a concentration of 100 to 600 ppm as product (based on slurry solids) in the mixed slurry.

**General Preservative Use:** Mergal GLT50 is recommended for use in aqueous or water containing products and systems, including industrial, institutional and consumer in-can processes and products, to control the growth of bacteria and fungi. For effective preservation, add Mergal GLT50 to the product formulation at a rate of 0.02% to 0.2% based on the water content of the product (0.2 to 2.0 pounds Mergal GLT50 per 1,000 pounds of water content). Mix uniformly.

**Preservatives for Concentrates:** For use in concentrates where effective preservation is needed after dilution, add Mergal GLT50 to the product formulation at a rate such that the diluted end-use product will contain 0.02% to 0.20% Mergal GLT50. At no time during the preservation process should the level of Mergal GLT50 exceed 2.0%.

**Process Water and Raw Material Clean-Up**

To reduce microbial contamination in process water or raw materials use to make industrial products, add Mergal GLT50 directly to the process water or raw material at a rate of 200 to 2,000 ppm by weight. Mix uniformly.

Usage rates vary depending on the raw material and the contamination/organic load as well as pH and matrix effects.

**Concrete Admixtures:** For effective preservation of concrete admixtures, add Mergal GLT50 to the product formulation at a rate of 2,000 to 8,000 ppm based on the weight of the admixture (2.0 to 8.0 pounds Mergal GLT50 per 1,000 pounds concrete admixture). Mix uniformly.

For further information on uses and use rates see Product Information Sheet.

**STORAGE AND HANDLING**

**STORAGE:** Keep container tightly closed when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances.

**HANDLING:** Mergal GLT50 is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. Mergal GLT50 can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 16° F (-9°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to 1 month), temperatures of up to 100°F (37.8°C) can be tolerated but the preferred maximum storage temperature is about 80°F (26.7°C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLO® Polymer is suitable for gaskets and packing.

Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

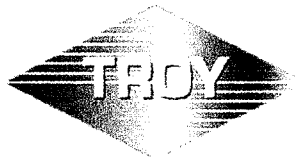
**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.  
**STORAGE:** Do not pour, spill or store near heat or open flame.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL: Refillable container.** Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full of water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat the rinsing procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities. **Non-Refillable container.** Do not reuse or refill container. Triple or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

14June2014MM



## **PRODUCT INFORMATION SHEET**

MERGAL® GLT50

EPA REG. NO. 5383-193

*This document must accompany each shipment of MERGAL GLT50*

### **DIRECTIONS FOR USE**

*It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.*

**AQUEOUS METALWORKING FLUIDS:** Mergal GLT50 should be added to a metal working fluid system at a point of uniform mixing such as the fluid collection tank. Additions may be made intermittently (SLUG DOSE) at intervals of one week or less.

**Initial Dose:** When the system is noticeably fouled, apply 2.4 to 7.2 fluid ounces (100 to 300 ppm active) of Mergal GLT50 per 100 gallons of metal working fluid to the system. Repeat until control is achieved.

**Subsequent Doses:** When microbial control is evident, add 0.95 to 4.8 fluid ounces (40 to 200 ppm active) of Mergal GLT50 per 100 gallons of metal working fluid to the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

**WATER BASED CONVEYOR LUBRICANTS (Brewery, Juice, Dairy, Beverage, and Food Processing Systems):** Avoid contamination of food in application of product. Thoroughly clean all tracks and conveyors to remove gross soil. Rinse well. Use an automatic feed system to provide 1.2 to 7.2 fluid ounces (50 to 300 ppm active) of Mergal GLT50 per 100 gallons of diluted lubricant.

**AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:** This product may be used only in industrial air washers and air washer systems which have mist-eliminating components. For control of microbial growth, Mergal GLT50 should be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as the basin area. Addition may be made intermittently (SLUG DOSE) or continuously. Badly fouled systems can be shock treated with MERGAL GLT50. Under these conditions, blowdown should be discontinued for up to 24 hours. MERGAL GLT50 can be used in industrial process water systems that contain ultra-filtration units and non-medical reverse osmosis membranes (where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### **INTERMITTENT (SLUG DOSE) METHOD**

**Initial dose:** When the system is noticeably fouled, apply 12 to 24 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system. Repeat until control is achieved.

**Subsequent dose:** When microbial control is evident, add 4.8 to 12 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system weekly, or as needed to maintain control. Badly fouled system must be cleaned before treatment is begun.

#### **CONTINUOUS FEED METHOD**

**Initial dose:** When the system is noticeably fouled, apply 12 to 24 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system.

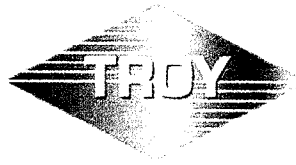
**Subsequent dose:** Maintain this treatment level by starting a continuous feed of 2.4 to 12 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system per day. Badly fouled system must be cleaned before treatment is begun.

**SERVICE WATER AND AUXILLARY SYSTEMS:** For control of microbial growth, MERGAL GLT50 should be used at the same application rates and in the same manner as described above. It should be added to the system at a point that will allow for uniform mixing throughout the system.

**HEAT TRANSFER SYSTEMS:** (Evaporative Condensers, Dairy Sweetwater Systems, Hydrostatic Sterilizers and Retorts, and Pasteurizers and Warmers) For control of microbial growth, MERGAL GLT50 should be used at the same application rates, and in the same manner as described above. It should be added to the system as a point of uniform mixing such as a basin area, sump area, or other reservoir or collection area from which the treated water will be circulated uniformly throughout the system.

**INDUSTRIAL WASTEWATER SYSTEMS:** (Wastewater system, wastewater sludge and wastewater holding tanks) MERGAL GLT50 should be added to a wastewater system or sludge at a convenient point of uniform mixing such as the digester. For control of microbial growth, add 5.4 to 27 fluid ounces (450 to 2,250 ppm) MERGAL GLT50 per 100 gallons of wastewater or sludge.





## **PRODUCT INFORMATION SHEET**

MERGAL® GLT50

EPA REG. NO. 5383-193

*This document must accompany each shipment of MERGAL GLT50*

**PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS** MERGAL GLT50 should be added to the paper making system at a point of uniform mixing such as the beaters, broke chest pump, save-all tank, or white water tank.

**Initial Dose:** When the system is noticeably contaminated, add 0.5 to 3.0 lbs. of MERGAL GLT50 per ton of pulp or paper (dry basis) as a slug dose. Repeat until control is achieved. Heavily fouled systems should be boiled out prior to initial treatment.

**Subsequent Dose:** When microbial control is evident, add 0.3 to 2.0 lbs. of MERGAL GLT50 per ton of pulp or paper (dry basis) as a slug dose as necessary to maintain control.

**PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD** (For use in food and non-food contact pigments and filler slurries). Use from 0.1 to 0.6 lbs. of MERGAL GLT50 per 1000 lbs. dry powder to produce a concentration of 100 to 600 ppm as product (based on slurry solids) in the mixed slurry.

### **REVERSE OSMOSIS MEMBRANES**

For effective preservation of reverse osmosis elements (where approved for compatibility by membrane manufacturer), immerse elements in a tank containing 0.2% to 2.0% MERGAL GLT50. MERGAL GLT50 can also be added to in-line recirculating systems for preservation of installed out-of-service reverse osmosis equipment (where approved for compatibility by membrane manufacturer). Add 0.2% to 2.0% MERGAL GLT50 to the tank in the circulating system. Maintain the concentration of MERGAL GLT50 by periodic addition to counteract any system leakage.

**WATER FLOODS:** Mergal GLT50 should be added to a water flood system at a point of uniform mixing for effective microbial control.

**Initial Treatment:** When the system is noticeably contaminated, add 100 to 5,000 ppm Mergal GLT50 to the system (0.1 to 4.7 gallons Mergal GLT50 per 1,000 gallons flood water). Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 20 to 5,000 ppm Mergal GLT50 (0.02 to 4.7 gallons Mergal GLT50 per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

Mergal GLT50 is especially recommended for controlling sulfate reducing bacteria in water to be used for polymer treated water-flood programs. Mergal GLT50 does not interfere with the viscosity characteristics of the polymer agent. Mergal GLT50 may be applied in systems used to treat injection water immediately ahead of water de-oiling equipment such as an air flotation unit in the clear water holding tank or at the suction side of the injection pump. Mergal GLT50 should be used full strength in concentration of 15 ppm of Mergal GLT50 on a continuous basis or in slug applications to 2,500 ppm of Mergal GLT50 or higher concentrations as needed (1/4 pint per 1,000 gallons equals approximately 15 ppm). A typical slug application is one quart per 1,000 gallons.

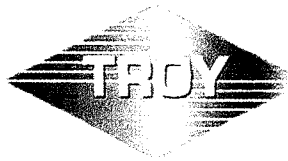
**FRAC FLUIDS (Product not registered for this use in the state of California):** Mergal GLT50 reduces bacterial contamination and degradation of fracturing fluids and gels used in oil and gas well stimulations. Add Mergal GLT50 to the frac water storage tanks or directly in to the well head injection pipeline as the water is being pumped down-hole. Dose range: Mergal GLT50 should be added at a rate of 100 to 5,000 ppm (0.95 to 47 gallons per 10,000 gallons) depending on the degree of bacterial fouling in the source water.

**DRILLING, COMPLETION and WORKOVER FLUIDS:** Mergal GLT50 should be added to a drilling fluid system at a point of uniform mixing such as the circulating mud tank.

**Initial treatment:** Add 50 to 1,000 ppm Mergal GLT50 (0.2 to 4.0 gallons Mergal GLT50 per 100 barrels of fluid) to a freshly prepared fluid depending on the severity of contamination.

**Maintenance dosage:** Maintain a concentration of 50 to 1,000 ppm Mergal GLT50 by adding 0.2 to 4.0 gallons of Mergal GLT50 per 100 barrels of additional fluid, or as needed, depending on the severity of contamination.

**PACKER FLUIDS:** Mergal GLT50 should be added to a packer fluid at a point of uniform mixing such as a circulating holding tank. Add 50 to 600 ppm Mergal GLT50 (0.2 to 2.4 gallons Mergal GLT50 per 100 barrels of fluid) to a freshly prepared fluid depending on the severity of contamination. Seal the treated packer fluid in the wall between the casing and production tube.



## **PRODUCT INFORMATION SHEET**

MERGAL® GLT50

EPA REG. NO. 5383-193

*This document must accompany each shipment of MERGAL GLT50*

**OIL PRODUCTION and TRANSMISSION PIPELINES and SYSTEMS (Not registered for this use in the state of California):** Mergal GLT50 should be added to an oil production or transmission line via direct injection. The application should be conducted to ensure maximum distribution of Mergal GLT50 throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect / measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in bacterial counts and / or reduced corrosion rates. To facilitate application, it may be desirable to dilute the Mergal GLT50 with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5,000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly or as needed to maintain control.

**GAS PRODUCTION and TRANSMISSION PIPELINES and SYSTEMS (Not registered for use in the state of California):** Mergal GLT50 should be added to a gas production or transmission line via direct injection. The application should be conducted to ensure maximum distribution of Mergal GLT50 throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect / measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in bacterial counts and / or reduced corrosion rates. To facilitate application, it may be desirable to dilute the Mergal GLT50 with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5,000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly or as needed to maintain control.

**GAS STORAGE WELLS and SYSTEMS:** Individual injection wells should be treated with sufficient quantity of Mergal GLT50 to produce a concentration of 500 to 5,000 ppm Mergal GLT50 when diluted by the water present in the formation. Injection should take place before gas is injected (during the summer). Injections should be repeated yearly, or as needed to maintain microbial control. Individual drips should be treated with a sufficient quantity of Mergal GLT50 to produce a concentration of 200 to 2,000 ppm Mergal GLT50 when diluted by the water present in the drip. Injections should be repeated yearly, or as needed to maintain control.

**HYDROTESTING:** Water used to hydro-test pipelines or vessels should contain 100 to 4,000 ppm Mergal GLT50 (0.1 to 3.8 gallons Mergal GLT50 per 1,000 gallons water), depending on water quality and length of time the equipment will remain idle.

**PIPELINE PIGGING and SCRAPING OPERATIONS:** Add Mergal GLT50 to a slug of water immediately following the scraper (ideally this water volume can be kept to a minimum and contained between the scraper and a trialing pig). Sufficient Mergal GLT50 should be added to produce a concentration of 0.1 to 1.0% (0.1 to 0.95 gallons Mergal GLT50 per 100 gallons water), depending on the length of the pipeline and the severity of biofouling.

TROY CHEMICAL CORPORATION  
One Avenue L  
Newark, N.J. 07105

14June2016MM

## Oiguenblik, Emilia

---

**From:** Murasaki, Seiichi  
**Sent:** Thursday, January 05, 2017 1:25 PM  
**To:** Oiguenblik, Emilia  
**Subject:** RE: 5383-192 and 5383-193 are not closed yet

Emilia,

I can help you with these. Julie left me the jacket for 5383-192. It looks like the FOIA team has the jacket for 5383-193.

Back in August, Julie sent Maureen an email outlining objections/deficiencies with these submissions; then in September, Maureen sent you an email with attachments.

For 5383-193, it appears that she wants to address the generic data compensation requirements with only a formulator's exemption (b)(5) DPP).

If 5383-192 is similar, let's handle in the same way.

Thanks!  
Seiichi

**From:** Oiguenblik, Emilia  
**Sent:** Wednesday, January 04, 2017 3:44 PM  
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>  
**Subject:** 5383-192 and 5383-193 are not closed yet

Hi Seiichi,

These submissions ( both of them are 302) are not logged out, and jackets are just signed for me.

Thanks,

Emilia Oiguenblik  
Antimicrobial Division  
S-8824  
Telephone: 703-347-0199  
Email: [Oiguenblik.Emilia@epa.gov](mailto:Oiguenblik.Emilia@epa.gov)



United States Environmental Protection Agency  
Washington, D.C. 20460

## Formulator's Exemption Statement (40 CFR 152.85)

Applicant's Name and Address Troy Chemical Corporation One Avenue L, Newark, N.J. 07105 c/o Troy Corporation 8 Vreeland Rd. Florham Park, N.J. 07932	EPA File Symbol/Registration Number <b>5383-193</b>
	Product Name <b>MERGAL GLT50</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>September 8, 2016</b>

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

**Glutaraldehyde**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:



(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**



(B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Glutaraldehyde, 50%	[REDACTED]	[REDACTED] <i>industrial strength</i>
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
	OR	OR
	[REDACTED]	[REDACTED]
Signature <i>Maureen Miksztal</i>	Name and Title Maureen Miksztal Senior Regulatory Manager	Date 9/8/2016

EPA Form 8570-27 (Rev. 7-91)

White - EPA copy

Yellow - Applicant copy

\*Product Source Information may be Entitled to Confidential Treatment\*

## Oiguenblik, Emilia

---

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[REDACTED]

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Emilia Oiguenblik  
Antimicrobial Division  
S-8824  
Telephone: 703-347-0199  
Email: [Oiguenblik.Emilia@epa.gov](mailto:Oiguenblik.Emilia@epa.gov)

## Oiguenblik, Emilia

---

**From:** Miksztal, Maureen <miksztalm@troycorp.com>  
**Sent:** Thursday, September 08, 2016 12:58 PM  
**To:** Chao, Julie; Oiguenblik, Emilia  
**Cc:** Hebert, John  
**Subject:** Response for additional information: 5383-192 and 5383-193 : Pending Label Amendment  
**Attachments:** 5383-193: Pending Label Amendment; MERGAL GLT50 cover ltr 08Sept16 signed.pdf; EPA8570-1 (PesticideApplicationForm) MERGAL GLT50 Amended 8Sept2016 signed.pdf; EPA8570-27 (Formulator'sExemption Statement) MERGAL GLT25 signed.pdf; EPA8570-27 (Formulator'sExemption Statement) MERGAL GLT50 8Sept2016 signed.pdf; EPA8570-1 (PesticideApplicationForm) MERGAL GLT25Amended 8Sept2016 signed.pdf

9/8/2016

Emilia,

Good afternoon. In Julie's absence, I am responding directly to you to provide additional support for the proposed pending label amendment for 5383-192 and 193. Please review the updated cover letter for substantiation of the proposed label change as well as the updated application amendment and formulators exemption statement to cover the substantially similar products and use.

Please let me know if you need anything further to complete the label amendment for 5383-192 and 193.

Thank you for your consideration.

Regards,

*Maureen*

Maureen Miksztal  
Senior Regulatory Manager  
Product Registration  
Troy Corporation | 8 Vreeland Road | Florham Park NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile

**TROY**

*This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error, please notify the sender immediately and delete this e-mail from your system. If you are not the intended recipient, you are notified that disclosing, copying, distributing, or taking any action on the contents of this information is strictly prohibited.*

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**From:** Chao, Julie [mailto:Chao.Julie@epa.gov]  
**Sent:** Saturday, August 27, 2016 1:22 PM  
**To:** Miksztal, Maureen  
**Subject:** 5383-192: Pending Label Amendment

Hi Maureen,

Same questions for 5383-192 as for 5383-193.

Thanks,  
Julie

**From:** Chao, Julie  
**Sent:** Saturday, August 27, 2016 1:16 PM  
**To:** 'Miksztal, Maureen' <miksztalm@troycorp.com>  
**Subject:** 5383-193: Pending Label Amendment

Hi Maureen,

Emilia Oiguenblik has been reviewing your label amendment application for 5383-193. I wanted to send you a direct note about label amendments and the paperwork that needs to be submitted as part of such applications to ensure efficient processing.

Because this amendment proposes to expand the current uses of the product, you need to be citing a similar registered product with the same application rates, and also addressing data and data compensation requirements. Box 6 on the 8570-1 application form is required for fast-track amendments.

Your product is a repack of several different potential sources, and it is not clear to me that the specific uses you are adding are on the labels of the products you are repacking. In particular, the "Process Water and Raw Material Clean-Up" use does not appear to match any of the uses on your source product labels. Typically, a product that is a repack of another product may not add additional uses not on the source label. Maybe I am not understanding the use pattern, but it seems to be broader and more generic than what is already on the label, suggesting that the product can be added to process water or raw materials in any type of industrial manufacturing setting.

As outlined in the Pesticide Registration Manual, these types of label amendments qualify for an expedited (i.e., fast-track) review when your application cites a similar product and its data. This allows us to do a quick comparison and ensure that the proposed use and application rates have already been reviewed and approved by EPA. In this case, it is not immediately clear to us what information is available to support your addition of "Process Water and Raw Material Clean-Up" use.

Below are some excerpts from the Pesticide Registration Manual. In the future, I think we will be able to ensure more efficient processing of applications if these requirements are met. In particular, any application that expands the existing uses of a product really needs to cite a similar product (Box 6 on the application form) and address generic data compensation. The data compensation can be addressed either through submission of a qualifying Formulator's Exemption statement (in this case, not clear if you qualify, since the source products do not appear to have this use on their labels), or through a properly filled out data matrix and data compensation form.

Please let me and Emilia know how you want to proceed with this amendment request. I'll be in the office Mon, Tue, Thurs, and Fri if you'd like to discuss over the phone. After September 5, I will be out of the office for five weeks, and John Hebert will be handling Team 33 business.

Thank you,

**From Chapter 6 of the Pesticide Registration Manual:  
Amendments Requiring No Scientific Review of Data (Fast Track)**

Fast track amendments include labeling changes or basic or alternate product formulation changes that do not require supporting data. Fast track amendments are also not subject to PRIA fees (for further information on PRIA fees, see Chapter 5).

If an amendment requests a change to a product that is “substantially similar” or “identical” to another product or “differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment” from another product, the similar or identical product and its applicable data may be cited instead of submitting required product-specific data. This amendment, now described as an “identical/substantially similar amendment,” was formerly called a “me-too” amendment. Each applicant applying for an “identical/substantially similar” amendment must comply with the data compensation procedures as discussed in FIFRA section 3(c)(1)(F). A discussion of these requirements and the applicable forms are in Chapter 10 of this manual.

**From Chapter 10 of the Pesticide Registration Manual:  
When Materials Must Be Submitted to the Agency**

Information and materials required to demonstrate compliance with data compensation procedures must be submitted at the time of application (40 CFR 152.84), unless it is determined that data compensation procedures do not apply to the application 40 CFR 152.81(b).

Some of the uses that are not subject to data compensation as described in 40 CFR 152.81(b) are described here: <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements#procedures>

Examples of properly completed data compensation forms are available in Appendix D of the Pesticide Registration Manual: <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>



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**TROY CORPORATION**

September 8, 2016

Via email

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL® GLT50, EPA Reg. No. 5383-193  
MERGAL® GLT25, EPA Reg. No. 5383-192  
Updated cover letter  
**Label Amendment**

Dear Ms. Chao:

Troy Corporation, on behalf of Troy Chemical Corporation, submitted a label amendment in June of 2016 to refine/clarify the general preservation use to include an additional paragraph in the directions for use for raw materials and process water used to make industrial products. This is not a new use, a new use pattern or a new dose rate for glutaraldehyde and all substantially similar glutaraldehyde products including those referenced on the application forms for Mergal GLT 25 and 50. This is a refinement of the preservation use currently approved for Mergal GLT 25 and 50 and all substantially similar glutaraldehyde products. It provides further clarity for the preservation application.

Noted below is a side-by-side comparison of the approved general preservative directions and the proposed process water/raw material directions:

**General Preservative Use:** Mergal GLT50 is recommended for use in aqueous or water containing products and systems, including industrial, institutional and consumer in-can processes and products, to control the growth of bacteria and fungi. For effective preservation, add Mergal GLT50 to the product formulation at a rate of 0.02% to 0.2% based on the water content of the product (0.2 to 2.0 pounds Mergal GLT50 per 1,000 pounds of water content). Mix uniformly.

**Process Water and Raw Material Clean-Up**

To reduce microbial contamination in process water or raw materials used to make industrial products, add Mergal GLT50 directly to the process water or raw material at a rate of 200 to 2,000 ppm by weight. Mix uniformly

The aforementioned preservation use and process water/raw material use is consistent with the industrial preservation use/labeling on a functional substantially similar product, 5383-154. This functional substantially similar



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## TROY CORPORATION

product is a DBNPA based biocide, Mergal 530 and like glutaraldehyde [Mergal GLT 50 and Mergal GLT 25] provides quick reductions in microbial load. An excerpt of the Mergal 530 label is noted below for comparison:

**Industrial Preservation:**

MERGAL 530 may be used to reduce microbiological contamination in raw materials and/or products such as: aqueous paints and coatings, polymers, slurries, adhesives, latex and resin emulsions, sizing, caulk, process water, along with specialty industrial products including: inks, polishes, waxes, detergents, and cleansers (**non-food uses only**). Add 25-2000 ppm by weight (2.8-224 fl. Oz.) per 1000 gals. or 21.4-1712 ml. per 1000 liters.

If EPA feels that there is a better approach to clarify preservation, we could adopt language similar to the Mergal 530 label as follows

**General Preservative Use:** Mergal GLT50 is recommended for use in raw materials and in aqueous or water containing products and systems, including industrial, institutional and consumer in-can processes and products and process water to control the growth of bacteria and fungi. For effective preservation, add Mergal GLT50 to the product formulation at a rate of 0.02% to 0.2% based on the water content of the product (0.2 to 2.0 pounds Mergal GLT50 per 1,000 pounds of water content). Mix uniformly.

Included under this cover, please find the following updated support documents for each registration:

- EPA Form 8570-1 Application form
- EPA Form 8570-27 Formulators Exemption

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or (973)443-4200 ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

Enclosure

Please read instructions on reverse before completing form.

Form Approved, 3 No. 2070-0060, Approval expires 05-31-98

 <b>EPA</b>	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b> <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other:</b>	OPP Identifier Number  
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### Application for Pesticide - Section I

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u><b>PLEASE SEND ALL CORRESPONDENCE TO</b></u> <u><b>"CONTACT POINT" LISTED BELOW</b></u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ _____ _____

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated 5/4/2016 <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**Label amendment modifies directions for use and adds a phrase to precautionary statements.**

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt.      No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.      No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* <b>Certification must be submitted</b>			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Maureen Mikszta	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (973) 443-4200 ext. 2285	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stamped)</b>
2. Signature 	3. Title Senior Regulatory Manager		
4. Typed Name Maureen Mikszta	5. Date 9/8/2016		



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**TROY CORPORATION**

June 14, 2016

Via CDX

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL® GLT50, EPA Reg. No. 5383-193  
**Label Amendment**

Dear Ms. Chao:

Troy Corporation, on behalf of Troy Chemical Corporation, hereby submits a label amendment for the product referenced above. The label amendment modifies the directions for use and further expands the existing preservation use to include raw materials and process water used to make industrial products. The label amendment also includes addition of a phrase to precautionary statements: "Avoid breathing vapor". No other changes were made to the label except the date on the label and the product information sheet and the placement of the metalworking fluid directions on the product information sheet from the label.

Included under this cover, please find the following support documents for each registration:

- Application form 8570-1
- 1 copy of updated label and product information sheet
- Highlighted versions of the label and product information sheet with revised wording highlighted in yellow

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [miksztalm@troycorp.com](mailto:miksztalm@troycorp.com) or (973)443-4200 ext. 2285.

Sincerely,


*Maureen Miksztal*

Maureen Miksztal  
Senior Regulatory Manager

Enclosure

DOCUMENTUM



 <b>EPA</b> United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number XXXXXX
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**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <b><u>PLEASE SEND ALL CORRESPONDENCE TO</u></b> <b><u>"CONTACT POINT" LISTED BELOW</u></b> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No  Product Name

**Section - II**

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated 5/4/2016
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)**Label amendment modifies directions for use and adds a phrase to precautionary statements.****Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Maureen Miksztal	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (973) 443-4200 ext. 2285	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stamped)</b>
2. Signature <i>Maureen Miksztal</i>	3. Title Senior Regulatory Manager		
4. Typed Name Maureen Miksztal	5. Date 6/14/2016		

DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 29, 2016

Maureen Miksztal  
Senior Regulatory Manager  
Troy Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

Subject: CSF Notification per PRN 98-10 – Updating Basic CSF  
Product Name: Mergal GLT50  
EPA Registration Number: 5383-193  
Application Date: August 4, 2016  
Decision Number: 520747

Dear Ms. Miksztal:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/11/2016
- Alternate CSF 1 dated 5/7/2016

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact me at (703) 308-8735 or by email at [chao.julie@epa.gov](mailto:chao.julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

**Chao, Julie**

---

**From:** Miksztal, Maureen <miksztalm@troycorp.com>  
**Sent:** Thursday, August 11, 2016 2:42 PM  
**To:** Chao, Julie  
**Subject:** Replacement Documents - MERGAL® GLT50, EPA Reg. No. 5383-193 for CSF Notification per PR Notice 98-10  
**Attachments:** MERGAL GLT50\_basiccfsf\_5383-193\_081116 signed.pdf; MERGAL GLT50 cover ltr 081116 Replacement documents signed.pdf; EPA8570-1 (PesticideApplicationForm) MERGAL GLT50 signed.pdf; 5383-193: Notification  
  
**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

August 11, 2016

Dear Ms. Chao:

Troy Corporation submitted a CSF notification on 8/4 to add an additional EPA establishment through CDX. After submission, an error was identified in the foreign establishment address. The Help Desk was contacted to withdraw the notification [Receipt number assigned: 989987] Unfortunately, this was not successful. Therefore, we are submitting replacement documents that correct the error in the establishment address.

Troy Corporation, on behalf of Troy Chemical Corporation, hereby re-submits a CSF Notification in accordance with PR Notice 98-10 for the product referenced above. This notification adds an additional production location to the basic CSF. No other changes have been made to the CSF.

Included under this cover, please find the following support documents for the CSF notification:

- Application form 8570-1
- Proposed Basic CSF dated August 11, 2016

Please confirm receipt of the replacement documents

Sorry for any inconvenience.

Regards,

*Maureen Miksztal*

Maureen Miksztal

Troy Corporation  
Senior Regulatory Manager  
8 Vreeland Road  
Florham Park, NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile  
Email: [miksztalm@troycorp.com](mailto:miksztalm@troycorp.com)



---

**TROY CORPORATION**

August 11, 2016

Via CDX

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193  
Replacement Documents  
**CSF Notification per PR Notice 98-10**

Dear Ms. Chao:

Troy Corporation submitted a CSF notification to add an additional EPA establishment through CDX. After submission, an error was identified in the foreign establishment address. The Help Desk was contacted to withdraw the notification. Unfortunately, this was not successful. Therefore, we are submitting replacement documents that correct the error in the establishment address.

Troy Corporation, on behalf of Troy Chemical Corporation, hereby re-submits a CSF Notification in accordance with PR Notice 98-10 for the product referenced above. This notification adds an additional production location to the basic CSF. No other changes have been made to the CSF.

Included under this cover, please find the following support documents for the CSF notification:

- Application form 8570-1
- Proposed Basic CSF dated August 11, 2016

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta1m@troycorp.com](mailto:mikszta1m@troycorp.com) or (973)443-4200 ext. 2285.

Sincerely,

*Maureen Miksztal*

Maureen Miksztal  
Senior Regulatory Manager

Enclosure

**EPA**

United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ **Registration**  
☐ **Amendment**  
☒ **Other:**

OPP Identifier Number

XXXXXX

**Application for Pesticide - Section I**

1. Company/Product Number  
 5383-193

4. Company/Product (Name)  
**MERGAL GLT50**

5. Name and Address of Applicant (Include ZIP Code)

**Troy Chemical Corporation**  
**c/o Troy Corporation**  
**8 Vreeland Road**  
**Florham Park, N.J. 07932**

**PLEASE SEND ALL CORRESPONDENCE TO**  
**"CONTACT POINT" LISTED BELOW**

☐ Check if this is a new address

2. EPA Product Manager  
 Julie Chao

PM#  
 33

3. Proposed Classification

☒ None ☐ Restricted

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No

Product Name

**Section - II**

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated \_\_\_\_\_

☒ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated 5/4/2016

☐ "Me Too" Application

☐ Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Troy Corporation is submitting a notification per PR Notice 98-10 and consists of addition of a new production location to the basic CSF. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

**Section - III**

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes\*  
☒ No

Unit Packaging

☐ Yes  
☒ No

Water Soluble Packaging

☐ Yes  
☒ No

2. Type of Container

☐ Metal  
☒ Plastic  
☐ Glass  
☐ Paper  
☐ Other (Specify)

**\*Certification must be submitted**

If "Yes" Unit Packaging wt. No. per container

If "Yes" Package wgt. No. per container

3. Location of Net Contents Information

☒ Label ☐ Container

4. Size(s) Retail Container

40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk

5. Location of Label Directions

☒ On Label  
☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph  
☒ Paper glued  
☐ Stenciled

☐ Other \_\_\_\_\_

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name  
 Maureen Miksztal

Title  
 Senior Regulatory Manager

Telephone No. (Include Area Code)  
 (973) 443-4200 ext. 2285

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

*Maureen Miksztal*

3. Title

Senior Regulatory Manager

4. Typed Name

Maureen Miksztal

5. Date  
 8/4/2016

6. Date Application Received  
**(Stamped)**



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 **ISB In Processing : 5383-193 S989987 2016-08-04**   
Description: 5383-193 S989987 2016-08-04  
From: Doc Admin  
Received: 8/4/2016 9:07 AM  
WorkFlow Instructions:

**cd\_13185\_989987 : Comments**

<u>Comment</u>	<u>Author</u>	<u>Date</u>
Non-PRIA	Hardy, Jacqueline	8/4/2016 9:06 AM
Notification		

[Add](#)



**EPA**

United States  
Environmental Protection Agency  
Washington, DC 20460

- ☐ Registration  
☐ Amendment  
☒ Other:

OPP Identifier Number

XXXXXX

**Application for Pesticide - Section I**1. Company/Product Number  
5383-1932. EPA Product Manager  
Julie Chao

3. Proposed Classification

4. Company/Product (Name)  
**MERGAL GLT50**PM#  
33☒ None ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

**Troy Chemical Corporation**  
c/o Troy Corporation  
8 Vreeland Road  
Florham Park, N.J. 07932

**PLEASE SEND ALL CORRESPONDENCE TO**  
**"CONTACT POINT" LISTED BELOW**

☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:  
EPA Reg. No

Product Name

**Section - II**☐ Amendment - Explain below.☐ Final printed labels in response to Agency letter dated 5/4/2016☐ Resubmission in response to Agency letter dated \_\_\_\_\_☐ "Me Too" Application☒ Notification - Explain below.☐ Other - Explain below**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Troy Corporation is submitting a notification per PR Notice 98-10 and consists of addition of a new production location to the basic CSF. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

**Section - III**

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes\*☒ No

Unit Packaging

☐ Yes☒ No

Water Soluble Packaging

☐ Yes☒ No

2. Type of Container

☐ Metal☒ Plastic☐ Glass☐ Paper☐ Other (Specify)

**\*Certification must  
be submitted**

If "Yes"

Unit Packaging wt.

No. per

container

If "Yes"

Package wgt.

No. per

container

3. Location of Net Contents Information

☒ Label☐ Container

4. Size(s) Retail Container

40 lb pail, 100 lb and 450 lb drum,  
2200 lb tote and bulk

5. Location of Label Directions

☒ On Label☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph☒ Paper glued☐ Stenciled☐ Other \_\_\_\_\_**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name

Maureen Mikszta

Title

Senior Regulatory Manager

Telephone No. (Include Area Code)

(973) 443-4200 ext. 2285

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application  
Received  
(Stamped)

2. Signature

*Maureen Mikszta*

3. Title

Senior Regulatory Manager

4. Typed Name

Maureen Mikszta

5. Date

8/4/2016



---

**TROY CORPORATION**

August 4, 2016

Via CDX

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193  
**CSF Notification per PR Notice 98-10**

Dear Ms. Chao:

Troy Corporation, on behalf of Troy Chemical Corporation, hereby submits a CSF Notification in accordance with PR Notice 98-10 for the product referenced above. This notification adds an additional production location to the basic CSF. No other changes have been made to the CSF.

Included under this cover, please find the following support documents for the CSF notification:

- Application form 8570-1
- Proposed Basic CSF dated August 4, 2016

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or (973)443-4200 ext. 2285.

Sincerely,

Maureen Mikszta  
Senior Regulatory Manager

Enclosure

DOCUMENTUM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 17, 2016

Maureen Miksztal  
Senior Regulatory Manager  
Troy Chemical Corporation  
c/o Troy Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

Subject: CSF Notification per PRN 98-10 – Add an Alternate CSF  
Product Name: Mergal® GLT50  
EPA Registration Number: 5383-193  
Application Date: May 6, 2016  
Decision Number: 517526

Dear Ms. Miksztal:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 4/7/2016
- Alternate CSF 1 dated 5/7/2016

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Emilia Oiguenblik by phone at (703) 347-0199, or via email at [Oiguenblik.emilia@epa.gov](mailto:Oiguenblik.emilia@epa.gov) or Julie Chao by phone at (703) 308-8735, or via email at [Chao.Julie@epa.gov](mailto:Chao.Julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", is positioned above the typed name.

Julie Chao, Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs



---

**TROY CORPORATION**

May 6, 2016

Via E-Portal

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193  
NOTIFICATION per PR Notice 98-10  
**Alternate CSF submission**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits a NOTIFICATION per PR notice 98-10 for an alternate CSF for MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193. The alternate CSF changes the registered source of active ingredient in accordance with PR notice 98-10. This action is eligible for the formulators' exemption since it is 100% repack of the new source.

This submission includes the following information using the e-portal:

- EPA Form 8570-1 Application for Registration
- EPA Form 8570-4 Proposed Alternate Confidential Statement of Formula
- EPA Form 8570-4 Current Basic Confidential Statement of Formula
- EPA Form 8570-27 Formulators Exemption

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input checked="" type="checkbox"/> <b>Other:</b>	OPP Identifier Number <div style="border: 1px solid black; padding: 5px; text-align: center;">XXXXXX</div>
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 5383-193		2. EPA Product Manager Julie Chao	
4. Company/Product (Name) <b>MERGAL GLT50</b>		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <b><u>PLEASE SEND ALL CORRESPONDENCE TO</u></b> <b><u>"CONTACT POINT" LISTED BELOW</u></b> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No Product Name	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below. <span style="margin-left: 200px;"><input type="checkbox"/> Final printed labels in response to Agency letter dated _____</span> <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <span style="margin-left: 200px;"><input type="checkbox"/> "Me Too" Application</span> <input checked="" type="checkbox"/> Notification - Explain below. <span style="margin-left: 200px;"><input checked="" type="checkbox"/> Other - Explain below</span>			
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.)  <b>Alternate CSF submission per PR Notice 98-10.</b> This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No  <b>*Certification must be submitted</b>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt.      No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.      No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name <b>Maureen Miksztal</b>	Title <b>Senior Regulatory Manager</b>	Telephone No. (Include Area Code) <b>(973) 443-4200 ext. 2285</b>	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="border: 1px solid black; padding: 5px; background-color: #f2f2f2;"><b>(Stamped)</b></div>
2. Signature 		3. Title <b>Senior Regulatory Manager</b>	
4. Typed Name <b>Maureen Miksztal</b>		5. Date <b>5/6/2016</b>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 29, 2016

Maureen Miksztal  
Senior Regulatory Manager  
Troy Chemical Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

Subject: Notification per PRN 98-10 – To correct typographical errors on the label  
Product Name: Mergal® GLT50  
EPA Registration Number: 5383-193  
Application Date: May 31, 2016  
Decision Number: 518479

Dear Ms. Miksztal:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Emilia Oiguenblik by phone at (703) 347-0199 or via email at [Oiguenblik.emilia@epa.gov](mailto:Oiguenblik.emilia@epa.gov), or Julie Chao by phone at (703) 308-8735 or via email at [Chao.Julie@epa.gov](mailto:Chao.Julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", is positioned above the typed name and title.

Julie Chao, Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER**

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if inhaled. Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none"> <li>Wash immediately and continuously with flowing water for at least 30 minutes.</li> <li>Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist.</li> <li>Call a poison control center or a doctor immediately for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED:	<ul style="list-style-type: none"> <li>Call a poison control center or doctor for treatment advice.</li> <li>Do not induce vomiting.</li> <li>Do not give anything to drink.</li> </ul>
IF INHALED:	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the MSDS and, if available, the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN:	
Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.	

**Mergal® GLT50**

Microbiocide for use in Air Washers, Coatings, Concrete Admixtures, Conveyor Lubricants, Completion and Drilling Fluids, Frac Fluids, Gas and Storage Wells, Heat Transfer Systems, Hydrotesting, Industrial, Institutional and Consumer In-can Processes and Products, Metal Working Fluids, Oil and Gas Production, Packer Fluids, Paper Mills, Pigment and Filler Slurries, Pipeline, Pigging and Scraping, Reverse Osmosis Membranes, Service Water and Auxiliary Systems, Wastewater Systems and Water floods.

EPA Reg. No.	5383-193
EPA Establishment Number	35978-TX-001

ACTIVE INGREDIENT:	% Weight
Glutaraldehyde.....	50.0%
INERT INGREDIENTS .....	50.0%
TOTAL .....	100.0%

**NOTIFICATION**

5383-193  
The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:  
6/29/2016

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

FOR USE IN INDUSTRIAL PROCESSES ONLY

See Side Panel for Additional Precautionary Statements

IN CASE OF EMERGENCY: CALL CHEMTREC 1-800-424-9300

Net Weight:

Sold by:

**Troy Chemical Corporation**  
One Avenue L, Newark, N.J. 07105

**DIRECTIONS FOR USE**

*It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.*

In order to determine the most cost effective use level for Mergal®GLT50 in a given use, field trials are suggested.

**Water Based Coatings (For use in non-food contact coatings only):** Use from 0.1 to 0.5 pounds of Mergal GLT50 per 1,000 pounds dry powder to produce a concentration of 100 to 500 ppm as product (based on slurry solids) in the mixed slurry.

**General Preservative Use:** Mergal GLT50 is recommended for use in aqueous or water containing products and systems, including industrial, institutional and consumer in-can processes and products, to control the growth of bacteria and fungi. For effective preservation, add Mergal GLT50 to the product formulation at a rate of 0.02% to 0.2% based on the water content of the product (0.2 to 2.0 pounds Mergal GLT50 per 1,000 pounds of water content). Mix uniformly.

**Preservatives for Concentrates:** For use in concentrates where effective preservation is needed after dilution, add Mergal GLT50 to the product formulation at a rate such that the diluted end-use product will contain 0.02% to 0.20% Mergal GLT50. At no time during the preservation process should the level of Mergal GLT50 exceed 2.0%.

**Concrete Admixtures:** For effective preservation of concrete admixtures, add Mergal GLT50 to the product formulation at a rate of 2,000 to 8,000 ppm based on the weight of the admixture (2.0 to 8.0 pounds Mergal GLT50 per 1,000 pounds concrete admixture). Mix uniformly.

**Aqueous Metal Working Fluids:** Mergal GLT50 should be added to a metal working fluid system at a point of uniform mixing such as the fluid collection tank. Additions may be made intermittently (SLUG DOSE) at intervals of one week or less.

**Initial Dose:** When the system is noticeably fouled, apply 2.4 to 7.2 fluid ounces (100 to 300 ppm active) of Mergal GLT50 per 100 gallons of metal working fluid to the system. Repeat until control is achieved.

**Subsequent Doses:** When microbial control is evident, add 0.95 to 4.8 fluid ounces (40 to 200 ppm active) of Mergal GLT50 per 100 gallons of metal working fluid to the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

For further information on uses and use rates see Product Information Sheet.

**STORAGE AND HANDLING**

**STORAGE:** Keep container closed when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances.

**HANDLING:** Mergal GLT50 is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. Mergal GLT50 can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy plastic equipment. This product freezes at about 16° F (-9°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to 1 month), temperatures of up to 100°F (37.8°C) can be tolerated but the preferred maximum storage temperature is about 80°F (26.7°C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLO® Polymer is suitable for gaskets and packing. Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Do not pour, spill or store near heat or open flame.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full of water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat the rinsing procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

**Non-Refillable container.** Do not reuse or refill container. Triple or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

51845y0161M





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**TROY CORPORATION**

May 31, 2016

Via CDX

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: **MERGAL<sup>®</sup> GLT50, EPA Reg. No. 5383-193**  
**Label Notification per PR Notice 98-10**

Dear Ms. Chao:

Troy Corporation, on behalf of Troy Chemical Corporation, hereby submits a label Notification in accordance with PR Notice 98-10 for the product referenced above. This notification corrects a typographical error in the ppm product conversion in the water based coatings directions on page 1 of the label. No other changes were made to the label except the date on the label and the product information sheet.

Included under this cover, please find the following support documents for each registration:

- Application form 8570-1
- 1 copy of updated label
- 1 copy of label with revised wording highlighted

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at [mikszta@mikszta.com](mailto:mikszta@mikszta.com) or (973)443-4200 ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

Enclosure

DOCUMENT

**EPA**

United States  
Environmental Protection Agency  
Washington, DC 20460

- ☐ Registration  
☐ Amendment  
☒ Other:

OPP Identifier Number  
XXXXXX

**Application for Pesticide - Section I**

1. Company/Product Number 5383-193	2. EPA Product Manager Julie Chao	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>MERGAL GLT50</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation c/o Troy Corporation 8 Vreeland Road Florham Park, N.J. 07932</b> <b><u>PLEASE SEND ALL CORRESPONDENCE TO</u></b> <b><u>"CONTACT POINT" LISTED BELOW</u></b> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No  Product Name

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated 5/4/2016
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)  
**Label notification to correct typo in ppm product conversion in water based coatings directions. No other changes were made to the label.** This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Maureen Mikszta	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (973) 443-4200 ext. 2285	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>Maureen Mikszta</i>	3. Title Senior Regulatory Manager		
4. Typed Name Maureen Mikszta	5. Date 5/31/2016		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 17, 2016

Maureen Miksztal  
Senior Regulatory Manager  
Troy Chemical Corporation  
c/o Troy Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

Subject: CSF Notification per PRN 98-10 – Add an Alternate CSF  
Product Name: Mergal® GLT50  
EPA Registration Number: 5383-193  
Application Date: May 6, 2016  
Decision Number: 517526

Dear Ms. Miksztal:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 4/7/2016
- Alternate CSF 1 dated 5/7/2016

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Emilia Oiguenblik by phone at (703) 347-0199, or via email at [Oiguenblik.emilia@epa.gov](mailto:Oiguenblik.emilia@epa.gov) or Julie Chao by phone at (703) 308-8735, or via email at [Chao.Julie@epa.gov](mailto:Chao.Julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs



---

TROY CORPORATION

May 6, 2016

Via E-Portal

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL® GLT50, EPA Reg. No. 5383-193  
NOTIFICATION per PR Notice 98-10  
**Alternate CSF submission**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits a NOTIFICATION per PR notice 98-10 for an alternate CSF for MERGAL® GLT50, EPA Reg. No. 5383-193. The alternate CSF changes the registered source of active ingredient in accordance with PR notice 98-10. This action is eligible for the formulators' exemption since it is 100% repack of the new source.

This submission includes the following information using the e-portal:

- EPA Form 8570-1 Application for Registration
- EPA Form 8570-4 Proposed Alternate Confidential Statement of Formula
- EPA Form 8570-4 Current Basic Confidential Statement of Formula
- EPA Form 8570-27 Formulators Exemption


Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at miksztalm@troycorp.com or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Miksztal*

Maureen Miksztal  
Senior Regulatory Manager

CONFIDENTIAL

 <b>EPA</b> United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input checked="" type="checkbox"/> <b>Other:</b>	OPP Identifier Number <div style="text-align: center; font-size: 1.2em;">XXXXXX</div>
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**Application for Pesticide - Section I**

1. Company/Product Number 5383-193 4. Company/Product (Name) <b>MERGAL GLT50</b>	2. EPA Product Manager Julie Chao PM# 33	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u><b>PLEASE SEND ALL CORRESPONDENCE TO</b></u> <u><b>"CONTACT POINT" LISTED BELOW</b></u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____

**Section - II**

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below
--	--


**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**Alternate CSF submission per PR Notice 98-10.** This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.    No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name <b>Maureen Mikszta</b>	Title <b>Senior Regulatory Manager</b>	Telephone No. (Include Area Code) <b>(973) 443-4200 ext. 2285</b>
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title <b>Senior Regulatory Manager</b>	
4. Typed Name <b>Maureen Mikszta</b>	5. Date <b>5/6/2016</b>	

# PROCESSING REQUEST

Reg. #: 5383 -193

Decision #: 513992

Description:

## Material Available Electronically (see PPLS):

☐ Electronic Label/Letter Dated:

☐ Other:

## Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐

☒ New CSF(s) Dated:

4/7/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer:

Joseph Daniels

Division: Antimicrobials Division

Phone: (703) 347-8669

Date: 5/4/16





## U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

5383-193

Date of Issuance:

5/4/16

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

MERGAL GLT50

## Name and Address of Registrant (include ZIP Code):

Maureen Miksztal  
Senior Regulatory Manager  
Troy Chemical Corporation  
c/o Troy Corporation  
8 Vreeland Road  
Florham Park, NJ 07932

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33  
Regulatory Management Branch 1, Antimicrobials Division (7510P)

Date:

5/4/16

2. You are required to comply with the data requirements described in the DCI identified below:

a. Glutaraldehyde GDCI-043901-30859

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 33): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>.

3. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 5383-193."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04/07/2016

If you have any questions, please contact Joe Daniels by phone at (703) 347-8669, or via email at [daniels.joseph@epa.gov](mailto:daniels.joseph@epa.gov).

Sincerely,



Julie Chao, Product Manager 33  
Regulatory Management Branch 1

Enclosure: Accepted Label

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER**

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if inhaled. Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

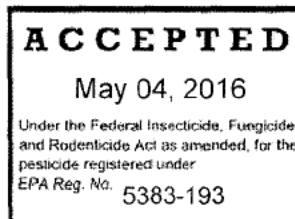
FIRST AID	
IF IN EYES:	<ul style="list-style-type: none"> <li>Wash immediately and continuously with flowing water for at least 30 minutes</li> <li>Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist.</li> <li>Call a poison control center or a doctor immediately for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED:	<ul style="list-style-type: none"> <li>Call a poison control center or doctor for treatment advice.</li> <li>Do not induce vomiting.</li> <li>Do not give anything to drink.</li> </ul>
IF INHALED:	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the MSDS and, if available, the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN:	
Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.	

# Mergal® GLT50

Microbiocide for use in Air Washers, Coatings, Concrete Admixtures, Conveyor Lubricants, Completion and Drilling Fluids, Frac Fluids, Gas and Storage Wells, Heat Transfer Systems, Hydrotesting, Industrial, Institutional and Consumer In-can Processes and Products, Metal Working Fluids, Oil and Gas Production, Packer Fluids, Paper Mills, Pigment and Filler Slurries, Pipeline, Pigging and Scraping, Reverse Osmosis Membranes, Service Water and Auxiliary Systems, Wastewater Systems and Water floods.

EPA Reg. No.	5383-TBD
EPA Establishment Number	35978-TX-001

ACTIVE INGREDIENT: ..... % Weight  
 Glutaraldehyde.....50.0%  
 INERT INGREDIENTS .....50.0%  
 TOTAL.....100.0%



**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

FOR USE IN INDUSTRIAL PROCESSES ONLY

See Side Panel for Additional Precautionary Statements

IN CASE OF EMERGENCY: CALL CHEMTREC 1-800-424-9300

Net Weight:

Sold by:

**Troy Chemical Corporation**  
 One Avenue L, Newark, N.J. 07105

**DIRECTIONS FOR USE**

*It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.*

In order to determine the most cost effective use level for Mergal®GLT50 in a given use, field trials are suggested.

**Water Based Coatings (For use in non-food contact coatings only):** Use from 0.1 to 0.6 pounds of Mergal GLT50 per 1,000 pounds dry powder to produce a concentration of 200 to 1,200 ppm as product (based on slurry solids) in the mixed slurry.

**General Preservative Use:** Mergal GLT50 is recommended for use in aqueous or water containing products and systems, including industrial, institutional and consumer in-can processes and products, to control the growth of bacteria and fungi. For effective preservation, add Mergal GLT50 to the product formulation at a rate of 0.02% to 0.2% based on the water content of the product (0.2 to 2.0 pounds Mergal GLT50 per 1,000 pounds of water content). Mix uniformly.

**Preservatives for Concentrates:** For use in concentrates where effective preservation is needed after dilution, add Mergal GLT50 to the product formulation at a rate such that the diluted end-use product will contain 0.02% to 0.20% Mergal GLT50. At no time during the preservation process should the level of Mergal GLT50 exceed 2.0%.

**Concrete Admixtures:** For effective preservation of concrete admixtures, add Mergal GLT50 to the product formulation at a rate of 2,000 to 8,000 ppm based on the weight of the admixture (2.0 to 8.0 pounds Mergal GLT50 per 1,000 pounds concrete admixture). Mix uniformly.

**Aqueous Metal Working Fluids:** Mergal GLT50 should be added to a metal working fluid system at a point of uniform mixing such as the fluid collection tank. Additions may be made intermittently (SLUG DOSE) at intervals of one week or less.

**Initial Dose:** When the system is noticeably fouled, apply 2.4 to 7.2 fluid ounces (100 to 300 ppm active) of Mergal GLT50 per 100 gallons of metal working fluid to the system. Repeat until control is achieved.

**Subsequent Doses:** When microbial control is evident, add 0.95 to 4.8 fluid ounces (40 to 200 ppm active) of Mergal GLT50 per 100 gallons of metal working fluid to the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

For further information on uses and use rates see Product Information Sheet.

**STORAGE AND HANDLING**

**STORAGE:** Keep container closed when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances.

**HANDLING:** Mergal GLT50 is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. Mergal GLT50 can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 16° F (-9°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to 1 month), temperatures of up to 100°F (37.8°C) can be tolerated but the preferred maximum storage temperature is about 80°F (26.7°C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLON® Polymer is suitable for gaskets and packing. Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

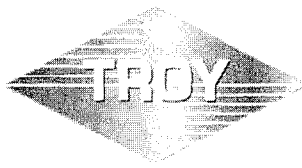
**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Do not pour, spill or store near heat or open flame.  
**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full of water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat the rinsing procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities. **Non-Refillable container.** Do not reuse or refill container. Triple or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

3May2016MM



## **PRODUCT INFORMATION SHEET**

MERGAL® GLT50

EPA REG. NO. 5383-TBD

*This document must accompany each shipment of MERGAL GLT50*

### **DIRECTIONS FOR USE**

*It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.*

**WATER BASED CONVEYOR LUBRICANTS (Brewery, Juice, Dairy, Beverage, and Food Processing Systems):** Avoid contamination of food in application of product. Thoroughly clean all tracks and conveyors to remove gross soil. Rinse well. Use an automatic feed system to provide 1.2 to 7.2 fluid ounces (50 to 300 ppm active) of Mergal GLT50 per 100 gallons of diluted lubricant.

**AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:** This product may be used only in industrial air washers and air washer systems which have mist-eliminating components. For control of microbial growth, Mergal GLT50 should be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as the basin area. Addition may be made intermittently (SLUG DOSE) or continuously. Badly fouled systems can be shock treated with MERGAL GLT50. Under these conditions, blowdown should be discontinued for up to 24 hours. MERGAL GLT50 can be used in industrial process water systems that contain ultra-filtration units and non-medical reverse osmosis membranes (where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### **INTERMITTENT (SLUG DOSE) METHOD**

Initial dose: When the system is noticeably fouled, apply 12 to 24 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system. Repeat until control is achieved.

Subsequent dose: When microbial control is evident, add 4.8 to 12 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system weekly, or as needed to maintain control. Badly fouled system must be cleaned before treatment is begun.

#### **CONTINUOUS FEED METHOD**

Initial dose: When the system is noticeably fouled, apply 12 to 24 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system.

Subsequent dose: Maintain this treatment level by starting a continuous feed of 2.4 to 12 fluid ounces of MERGAL GLT50 per 1000 gallons of water in the system per day. Badly fouled system must be cleaned before treatment is begun.

**SERVICE WATER AND AUXILIARY SYSTEMS:** For control of microbial growth, MERGAL GLT50 should be used at the same application rates and in the same manner as described above. It should be added to the system at a point that will allow for uniform mixing throughout the system.

**HEAT TRANSFER SYSTEMS:** (Evaporative Condensers, Dairy Sweetwater Systems, Hydrostatic Sterilizers and Retorts, and Pasteurizers and Warmers) For control of microbial growth, MERGAL GLT50 should be used at the same application rates, and in the same manner as described above. It should be added to the system as a point of uniform mixing such as a basin area, sump area, or other reservoir or collection area from which the treated water will be circulated uniformly throughout the system.

**INDUSTRIAL WASTEWATER SYSTEMS:** (Wastewater system, wastewater sludge and wastewater holding tanks) MERGAL GLT50 should be added to a wastewater system or sludge at a convenient point of uniform mixing such as the digester. For control of microbial growth, add 5.4 to 27 fluid ounces (450 to 2,250 ppm) MERGAL GLT50 per 100 gallons of wastewater or sludge.

**PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS** MERGAL GLT50 should be added to the paper making system at a point of uniform mixing such as the beaters, broke chest pump, save-all tank, or white water tank.

**Initial Dose:** When the system is noticeably contaminated, add 0.5 to 3.0 lbs. of MERGAL GLT50 per ton of pulp or paper (dry basis) as a slug dose. Repeat until control is achieved. Heavily fouled systems should be boiled out prior to initial treatment.

**Subsequent Dose:** When microbial control is evident, add 0.3 to 2.0 lbs. of MERGAL GLT50 per ton of pulp or paper (dry basis) as a slug dose as necessary to maintain control.



## **PRODUCT INFORMATION SHEET**

MERGAL® GLT50

EPA REG. NO. 5383-TBD

*This document must accompany each shipment of MERGAL GLT50*

**PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD** (For use in food and non-food contact pigments and filler slurries). Use from 0.1 to 0.6 lbs. of MERGAL GLT50 per 1000 lbs. dry powder to produce a concentration of 100 to 600 ppm as product (based on slurry solids) in the mixed slurry.

### **REVERSE OSMOSIS MEMBRANES**

For effective preservation of reverse osmosis elements (where approved for compatibility by membrane manufacturer), immerse elements in a tank containing 0.2% to 2.0% MERGAL GLT50. MERGAL GLT50 can also be added to in-line recirculating systems for preservation of installed out-of-service reverse osmosis equipment (where approved for compatibility by membrane manufacturer). Add 0.2% to 2.0% MERGAL GLT50 to the tank in the circulating system. Maintain the concentration of MERGAL GLT50 by periodic addition to counteract any system leakage.

**WATER FLOODS:** Mergal GLT50 should be added to a water flood system at a point of uniform mixing for effective microbial control.

**Initial Treatment:** When the system is noticeably contaminated, add 100 to 5,000 ppm Mergal GLT50 to the system (0.1 to 4.7 gallons Mergal GLT50 per 1,000 gallons flood water). Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 20 to 5,000 ppm Mergal GLT50 (0.02 to 4.7 gallons Mergal GLT50 per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

Mergal GLT50 is especially recommended for controlling sulfate reducing bacteria in water to be used for polymer treated water-flood programs. Mergal GLT50 does not interfere with the viscosity characteristics of the polymer agent. Mergal GLT50 may be applied in systems used to treat injection water immediately ahead of water de-oiling equipment such as an air flotation unit in the clear water holding tank or at the suction side of the injection pump. Mergal GLT50 should be used full strength in concentration of 15 ppm of Mergal GLT50 on a continuous basis or in slug applications to 2,500 ppm of Mergal GLT50 or higher concentrations as needed (1/4 pint per 1,000 gallons equals approximately 15 ppm). A typical slug application is one quart per 1,000 gallons.

**FRAC FLUIDS (Product not registered for this use in the state of California):** Mergal GLT50 reduces bacterial contamination and degradation of fracturing fluids and gels used in oil and gas well stimulations. Add Mergal GLT50 to the frac water storage tanks or directly in to the well head injection pipeline as the water is being pumped down-hole. Dose range: Mergal GLT50 should be added at a rate of 100 to 5,000 ppm (0.95 to 47 gallons per 10,000 gallons) depending on the degree of bacterial fouling in the source water.

**DRILLING, COMPLETION and WORKOVER FLUIDS:** Mergal GLT50 should be added to a drilling fluid system at a point of uniform mixing such as the circulating mud tank.

**Initial treatment:** Add 50 to 1,000 ppm Mergal GLT50 (0.2 to 4.0 gallons Mergal GLT50 per 100 barrels of fluid) to a freshly prepared fluid depending on the severity of contamination.

**Maintenance dosage:** Maintain a concentration of 50 to 1,000 ppm Mergal GLT50 by adding 0.2 to 4.0 gallons of Mergal GLT50 per 100 barrels of additional fluid, or as needed, depending on the severity of contamination.

**PACKER FLUIDS:** Mergal GLT50 should be added to a packer fluid at a point of uniform mixing such as a circulating holding tank. Add 50 to 600 ppm Mergal GLT50 (0.2 to 2.4 gallons Mergal GLT50 per 100 barrels of fluid) to a freshly prepared fluid depending on the severity of contamination. Seal the treated packer fluid in the wall between the casing and production tube.

**OIL PRODUCTION and TRANSMISSION PIPELINES and SYSTEMS (Not registered for this use in the state of California):** Mergal GLT50 should be added to an oil production or transmission line via direct injection. The application should be conducted to ensure maximum distribution of Mergal GLT50 throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect / measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in bacterial counts and / or reduced corrosion rates. To facilitate application, it may be desirable to dilute the Mergal GLT50 with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5,000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly or as needed to maintain control.



## **PRODUCT INFORMATION SHEET**

MERGAL® GLT50

EPA REG. NO. 5383-TBD

*This document must accompany each shipment of MERGAL GLT50*

**GAS PRODUCTION and TRANSMISSION PIPELINES and SYSTEMS (Not registered for use in the state of California):** Mergal GLT50 should be added to a gas production or transmission line via direct injection. The application should be conducted to ensure maximum distribution of Mergal GLT50 throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect / measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in bacterial counts and / or reduced corrosion rates. To facilitate application, it may be desirable to dilute the Mergal GLT50 with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5,000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly or as needed to maintain control.

**GAS STORAGE WELLS and SYSTEMS:** Individual injection wells should be treated with sufficient quantity of Mergal GLT50 to produce a concentration of 500 to 5,000 ppm Mergal GLT50 when diluted by the water present in the formation. Injection should take place before gas is injected (during the summer). Injections should be repeated yearly, or as needed to maintain microbial control. Individual drips should be treated with a sufficient quantity of Mergal GLT50 to produce a concentration of 200 to 2,000 ppm Mergal GLT50 when diluted by the water present in the drip. Injections should be repeated yearly, or as needed to maintain control.

**HYDROTESTING:** Water used to hydro-test pipelines or vessels should contain 100 to 4,000 ppm Mergal GLT50 (0.1 to 3.8 gallons Mergal GLT50 per 1,000 gallons water), depending on water quality and length of time the equipment will remain idle.

**PIPELINE PIGGING and SCRAPING OPERATIONS:** Add Mergal GLT50 to a slug of water immediately following the scraper (ideally this water volume can be kept to a minimum and contained between the scraper and a trialing pig). Sufficient Mergal GLT50 should be added to produce a concentration of 0.1 to 1.0% (0.1 to 0.95 gallons Mergal GLT50 per 100 gallons water), depending on the length of the pipeline and the severity of biofouling.

TROY CHEMICAL COMPANY

One Avenue L

Newark, N.J. 07105

27April2016MM



## Daniels, Joseph

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**From:** Miksztal, Maureen <miksztalm@troycorp.com>  
**Sent:** Tuesday, May 03, 2016 4:35 PM  
**To:** Daniels, Joseph  
**Subject:** Updated label submission - first aid hierarchy EPA Registration No. 5383-ROE and 5383-ROG  
**Attachments:** 5383-193-20160427\_LabelCorrections.pdf; 005383-00TBD\_20160208\_PRODUCT INFORMATION SHEET MERGALGLT25.pdf; 005383-00TBD\_20160503\_MERGAL GLT25 label clean copy.pdf; 005383-00TBD\_20160503\_MERGAL GLT25 label highlighted.pdf; 005383-00TBD\_20160208\_MERGAL GLT50 label clean copy.pdf; 005383-00TBD\_20160208\_MERGAL GLT50 label highlighted.pdf; 005383-00TBD\_20160208\_PRODUCT INFORMATION SHEET MERGAL GLT50.pdf; RE: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

5/3/2016

Joseph,

Thanks for your feedback. Troy has updated the glutaraldehyde labels to reflect first aid hierarchy that matches the identical order of the precautionary statements. Please see updated labels attached. Both highlighted and clean versions of the first page of the label are attached as well as a copy of the second page – product information sheet.

Let me know if you need anything else on the label review.

Regards,

*Maureen Miksztal*

Maureen Miksztal

Troy Corporation  
Senior Regulatory Manager  
8 Vreeland Road  
Florham Park, NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile  
Email: [miksztalm@troycorp.com](mailto:miksztalm@troycorp.com)

**From:** Daniels, Joseph [mailto:[Daniels.Joseph@epa.gov](mailto:Daniels.Joseph@epa.gov)]  
**Sent:** Wednesday, April 27, 2016 3:18 PM  
**To:** Miksztal, Maureen  
**Cc:** Chao, Julie  
**Subject:** RE: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG



Hello again! I just reviewed the labels, and it looks like most comments were addressed. I am attaching a copy of Mergal GLT50's label and Product Information Sheet with changes highlighted/noted. Please let me know if you have any more questions at your earliest convenience.

Joe Daniels

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
**Sent:** Wednesday, April 27, 2016 2:06 PM  
**To:** Daniels, Joseph <[Daniels.Joseph@epa.gov](mailto:Daniels.Joseph@epa.gov)>  
**Subject:** RE: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

Thank you

---

**From:** Daniels, Joseph [<mailto:Daniels.Joseph@epa.gov>]  
**Sent:** Wednesday, April 27, 2016 2:06 PM  
**To:** Miksztal, Maureen  
**Subject:** RE: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

Alright, I called IT and was able to track them down. Sorry for the confusion.

Joe

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
**Sent:** Wednesday, April 27, 2016 2:04 PM  
**To:** Daniels, Joseph <[Daniels.Joseph@epa.gov](mailto:Daniels.Joseph@epa.gov)>  
**Subject:** FW: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

There are 8 Attachments

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**From:** Miksztal, Maureen  
**Sent:** Wednesday, April 27, 2016 11:21 AM  
**To:** 'Daniels, Joseph'  
**Cc:** Chao, Julie  
**Subject:** Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

4/27/2016

Joseph,

Thank you for your thorough review of our pending glutaraldehyde registrations. Attached are updated revised labels for your review. Changes are highlighted in yellow.

Each of your observations from your email was reviewed for each label. See specific comments below for each observation:

- In-can, refers to materials preservation. This use is on the first page of both labels under general preservation use. A hyphen has been added to in-can in the directions for use and in the identifying statement.
- After reviewing [REDACTED] for comparison of first aid order, I can confirm that the most severe end point is listed first: "If swallowed" due to

\*Product ingredient source information may be entitled to confidential treatment\*

"may be fatal if swallowed" wording followed by eyes and skin due to corrosive nature of chemical.

- Final disposal instructions have been added to each label as well as instructions for non-refillable containers
- The spelling comment needs to be revisited - Is this not the correct spelling of:aux·il·ia·ry? Also check [REDACTED] for their spelling of the word.
- EPA Reg no is now corrected

Let me know if anything further is needed on these pending registrations.

Regards,

*Maureen Miksztal*

Maureen Miksztal

Troy Corporation  
Senior Regulatory Manager  
8 Vreeland Road  
Florham Park, NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile  
Email: [miksztalm@troycorp.com](mailto:miksztalm@troycorp.com)

---

**From:** Daniels, Joseph [<mailto:Daniels.Joseph@epa.gov>]  
**Sent:** Tuesday, April 26, 2016 9:37 AM  
**To:** Miksztal, Maureen  
**Cc:** Chao, Julie  
**Subject:** EPA Registration No. 5383-ROE and 5383-ROG

Good morning,

After review of the labels for these two registration, I have a question and a few comments that apply to both products. First of all, what are Industrial, Institutional, and Consumer Incan Processes and Products? I am assuming that Incan should read "in can," but I could not locate either of those in the label or Product Information Sheet. Are there specific In Can use directions, or are they represented within other product use directions? Also, please make sure that the order of the first aid statements directly reflects toxicity category (from most severe to least severe). In addition, please provide final disposal instructions in the storage and disposal section of the labels.

On the 5383-ROE label, please change the EPA Reg. No. to represent your company number.  
On 5383-ROG, please correct the spelling of the word Auxiliary (spelled auxillary) in Service Water and Auxiliary Systems of the Product Information Sheet.

Please let me know if you have any questions.

Joe

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
**Sent:** Thursday, April 07, 2016 4:18 PM  
**To:** Daniels, Joseph <[Daniels.Joseph@epa.gov](mailto:Daniels.Joseph@epa.gov)>  
**Subject:** RE: Submission of updated CSF for MERGAL GLT25, EPA Registration No. 5383-ROE

thx

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**From:** Daniels, Joseph [<mailto:Daniels.Joseph@epa.gov>]  
**Sent:** Thursday, April 07, 2016 4:17 PM  
**To:** Miksztal, Maureen  
**Subject:** RE: Submission of updated CSF for MERGAL GLT25, EPA Registration No. 5383-ROE

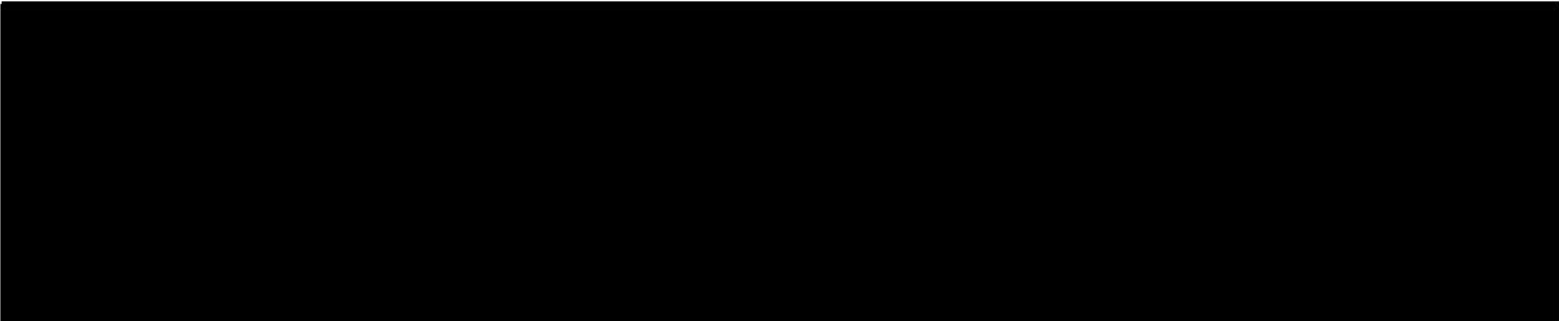
Maureen-

Wow, thanks for the second quick response of the day! I just went ahead and filed away the new CSF and will work on processing it. Have a great rest of your afternoon!

Joe

**From:** Miksztal, Maureen [<mailto:miksztalm@troycorp.com>]  
**Sent:** Thursday, April 07, 2016 4:08 PM  
**To:** Daniels, Joseph <[Daniels.Joseph@epa.gov](mailto:Daniels.Joseph@epa.gov)>  
**Cc:** Krygsman, Adrian <[KrygsmaA@troycorp.com](mailto:KrygsmaA@troycorp.com)>; Chao, Julie <[Chao.Julie@epa.gov](mailto:Chao.Julie@epa.gov)>  
**Subject:** Submission of updated CSF for MERGAL GLT25, EPA Registration No. 5383-ROE

**Business Confidential**



Regards,

*Maureen Miksztal*

\*Claimed confidential by submitter\*

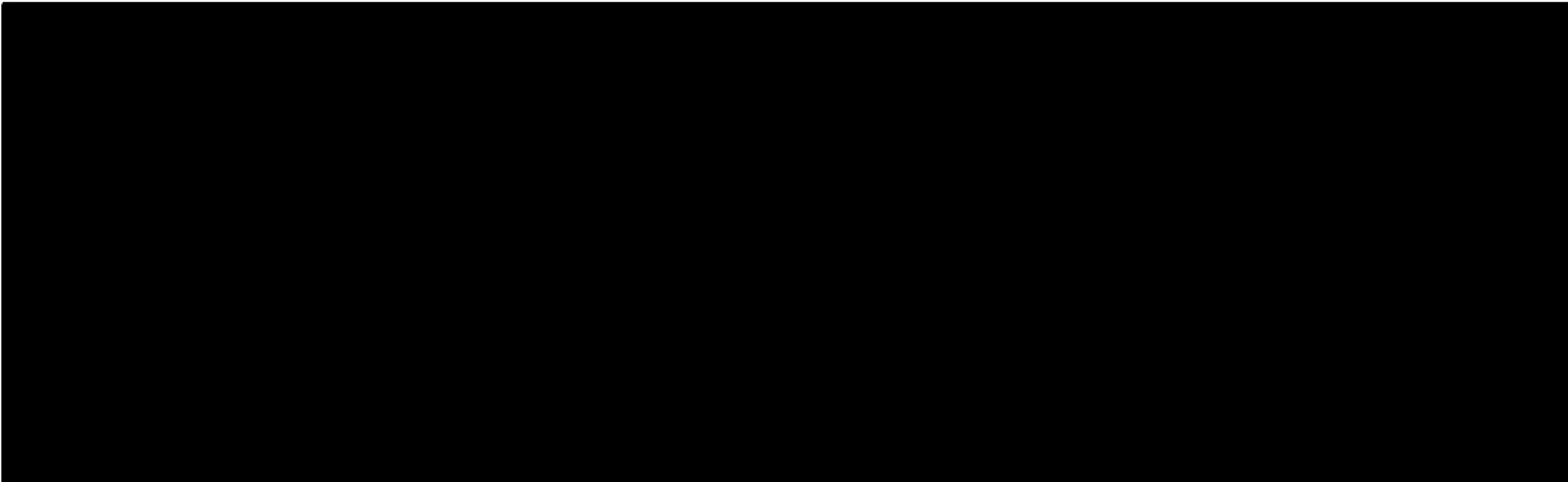
Maureen Miksztal

Troy Corporation  
Senior Regulatory Manager  
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Florham Park, NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile  
Email: [miksztalm@troycorp.com](mailto:miksztalm@troycorp.com)

**From:** Miksztal, Maureen  
**Sent:** Thursday, April 07, 2016 2:18 PM  
**To:** 'daniels.joseph@epa.gov'  
**Cc:** Krygsman, Adrian ([KrygsmaA@troycorp.com](mailto:KrygsmaA@troycorp.com)); Chao, Julie  
**Subject:** Submission of updated CSF for MERGAL GLT50, EPA Registration No. 5383-ROG

Business Confidential

4/7/2016



Regards,

\*Claimed confidential by submitter\*

*Maureen Miksztal*

Maureen Miksztal

Troy Corporation  
Senior Regulatory Manager  
8 Vreeland Road  
Florham Park, NJ 07932  
(973) 443-4200 Ext. 2285  
(973) 216-1083 Mobile  
Email: [miksztalm@troycorp.com](mailto:miksztalm@troycorp.com)



## Daniels, Joseph

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**From:** Miksztal, Maureen <miksztalm@troycorp.com>  
**Sent:** Monday, May 02, 2016 4:04 PM  
**To:** Chao, Julie; Daniels, Joseph  
**Subject:** RE: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

5/2/2016

Joe,

Thank you. I am back in the office and will get you updated labels tomorrow.

Regards,

Maureen

**From:** Chao, Julie [mailto:Chao.Julie@epa.gov]  
**Sent:** Wednesday, April 27, 2016 3:56 PM  
**To:** Miksztal, Maureen; Daniels, Joseph  
**Subject:** RE: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

Hi Maureen,

Thanks for getting in touch. Joe and I did discuss this, and I also confirmed with John Hebert earlier today.

As eye and skin irritation are ranked as Category I, these are the most severe routes of exposure. Acute oral toxicity, at Category II, is considered less severe. Therefore, under the First Aid section, the statements for "If in Eyes" and "If on Skin and Clothing" need to appear before the First Aid statements for "If Swallowed."

I can see how it might seem like oral toxicity is the most severe route of exposure, because of potential fatality, but the Agency actually considers irreversible eye and skin damage (leading to permanent blindness and severe permanent skin damage) to be the most severe. Category I will always be treated as more severe than Category II, regardless of whether the route is irritation or toxicity (this is what I confirmed with John).

The [REDACTED] label is incorrect; a lot of labels are incorrect, unfortunately. We are working to improve that as those labels come in for amendments, and we are also trying to catch this for new products. We definitely don't view it as an imminent risk issue, and as a result I'm sure we have missed some in the recent past, so I apologize if this has caused confusion about the preferred ordering of statements.

Let me know if you want to chat more over the phone.

Thanks much,  
Julie

**From:** Miksztal, Maureen [mailto:miksztalm@troycorp.com]  
**Sent:** Wednesday, April 27, 2016 3:34 PM  
**To:** Daniels, Joseph <Daniels.Joseph@epa.gov>  
**Cc:** Chao, Julie <Chao.Julie@epa.gov>  
**Subject:** FW: Comments on label questions: EPA Registration No. 5383-ROE and 5383-ROG

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 2-9-16

Experts In-Processing Signature: B.B. Date 2-19-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>5383 - ROG</u>		EPA Receipt Date: <u>2-9-16</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <i>no inerts to review. input Re-Pack</i>	yes	no			
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	<b>Data Matrix</b> (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					X
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (Electronic labels on CD are encouraged and guidance is available)			X		
7	<b>Is the data package consistent with PR Notice 86-5</b>					X
8	<b>Notice of Filing</b> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

\* Documentation: Pass / Fail  
 - Required forms are complete

\* Trends: Pass / Fail  
 - no trends to review. 100% Re-Pack

\* PRN 11-3: Pass / Fail  
 - no studies submitted

DN 2-25-16

\* Overall Status: Pass / Fail





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 19, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-513992  
EPA File Symbol or Registration Number: 5383-ROG  
Product Name: MERGAL GLT50  
EPA Receipt Date: 09-Feb-2016  
EPA Company Number: 5383  
Company Name: TROY CHEMICAL CORPORATION

MS. MAUREEN MIKSZTAL  
TROY CHEMICAL CORPORATION  
C/O TROY CORPORATION  
ONE AVENUE L  
NEWARK, NJ 07105-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A530

ME-TOO;NEW PRODUCT;FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

A handwritten signature in black ink, appearing to be "W. J. H.", written over the printed name.

Front End Processing Staff  
Information Technology & Resources Management Division





## EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: February 8, 2016

SUBMITTER: **Troy Chemical Corporation**  
**One Avenue L**  
**Newark, N.J. 07105**

**c/o**  
**Troy Corporation**  
**8 Vreeland Road**  
**Florham Park, N.J. 07932**

REGULATORY ACTION  
IN SUPPORT OF WHICH  
THIS IS SUBMITTED: **Application for Registration of a New End Use Pesticide Product**

PRODUCT NAME: **MERGAL<sup>®</sup> GLT50**

REGISTRATION NO.: **EPA Reg. No. 5383\_\_\_\_\_ (not yet assigned)**

STUDIES SUBMITTED:

Study Volume 1 of 1    **Administrative Materials** – forms and correspondence  
-Transmittal letter  
-EPA Form 8570-1 Application for Registration  
-EPA Form 8570-4 Confidential Statement of Formula (CSF)  
-EPA Form 8570-27 Formulators Exemption  
-Proposed product label for MERGAL GLT50  
-Copy of PRIA Fee Payment

**Company Contact:** **Maureen Mikszta**  
**Senior Regulatory Manager**  
**Troy Corporation**  
**8 Vreeland Road**  
**Florham Park, NJ 07932**  
**(973) 443-4200, X2285**

DOCUMENTUM



February 8, 2016

Via E-Portal

Document Processing Desk (REG)  
Office of Pesticide Programs (7504P)  
Antimicrobial Division (AD)  
U.S. EPA  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Attention: Ms. Julie Chao, PM 33

RE: MERGAL® GLT50, EPA Reg. No. 5383-TBD  
**Submission of Registration Application**

Dear Ms. Chao:

On behalf of Troy Chemical Corporation, Troy Corporation hereby submits a registration application for the end use product, MERGAL® GLT50. MERGAL GLT25 is 100% repack of the registered end use product: [REDACTED] or 100% repack of the registered end use product: [REDACTED] and is eligible for the formulators' exemption.

The application includes the following information using the e-portal:

Study Volume 1 of 1

**Administrative Materials** – forms and correspondence

- Transmittal letter
- EPA Form 8570-1 Application for Registration
- EPA Form 8570-4 Confidential Statement of Formula
- EPA Form 8570-27 Formulators Exemption
- Proposed product label
- Copy of PRIA Fee Payment

Please contact me directly should you have any questions concerning this action. I can be reached via email or phone at mikszta@mikszta.com or 973-443-4200, ext. 2285.

Sincerely,

*Maureen Mikszta*

Maureen Mikszta  
Senior Regulatory Manager

DOCUMENTUM

\*Product ingredient source information may be entitled to confidential treatment\*

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other:</b>	OPP Identifier Number <b>XXXXXX</b>
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number <b>5383-TBD</b>		2. EPA Product Manager <b>Julie Chao</b>	
4. Company/Product (Name) <b>MERGAL GLT50</b>		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) <b>Troy Chemical Corporation</b> <b>c/o Troy Corporation</b> <b>8 Vreeland Road</b> <b>Florham Park, N.J. 07932</b> <u><b>PLEASE SEND ALL CORRESPONDENCE TO</b></u> <u><b>"CONTACT POINT" LISTED BELOW</b></u> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below	
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.) Submission of New Product Registration: Proposed PRIA Classification - A530 New End Use Product, Registered Active Ingredient; 100% repack Fee \$1278.00 Company Contact Information: <b>Maureen Mikszta</b> FAX Number: (973)443-0258 mikszta@m@troycorp.com			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.    No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <b>40 lb pail, 100 lb and 450 lb drum, 2200 lb tote and bulk</b>	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name <b>Maureen Mikszta</b>		Title <b>Senior Regulatory Manager</b>	
		Telephone No. (Include Area Code) <b>(973) 443-4200 ext. 2285</b>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stamped)</b>
2. Signature 		3. Title <b>Senior Regulatory Manager</b>	
4. Typed Name <b>Maureen Mikszta</b>		5. Date <b>2/9/2016</b>	

Pages 86-92 \*CSF May be Entitled to Confidential Treatment\*